Advancing Generic Drug Development (AGDD) Virtual Workshop: Bioequivalence Challenges for Patient-Centric Oral Formulations

June 11, 2026, 8:30am – 12:30pm EDT

8:30 – 8:35 am — Welcome and Overview

Kori Adair, PharmD
Pharmacist
Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Center for Drug Evaluation and Research (CDER)

8:35 – 8:45 am — Current Landscape of Patient-Centric Formulations in Generic Drug Development: Gaps and Alternative Pathways

Karen Li, PharmD
Staff Fellow
Division of Therapeutic Performance II (DTP II)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER

8:45 – 9:00 am — Developing Pediatric Formulations: Regulatory Considerations

Vilayat Sayeed, PhD
Division Director
Division of Product Quality Assessment II
Office of Product Quality Assessment I (OPQA I)
Office of Pharmaceutical Quality (OPQ) | CDER

9:00 – 9:15 am — Suitability Petitions: An Avenue for Patient-Centric Formulations

Andrew Fine, PharmD
Associate Director for Regulatory Affairs
Office of Safety and Clinical Evaluation
OGD | CDER

9:15 – 9:30 am — Extrapolation Using PBPK Modeling to Support the Development of Pediatric Products

Fang Wu, PhD
Senior Pharmacologist
Division of Quantitative Methods and Modeling
ORS | OGD | CDER

9:30 – 10:00 am Question and Answer Session

Moderator:

Jihong Shon, MD, PhD
Associate Director for Clinical Safety
DTP II | ORS | OGD | CDER

Karen Li, PharmD
Vilayat Sayeed, PhD
Andrew Fine, PhD
Fang Wu, PhD

and joined by:

Meirong Hao, MS
Lead Pharmacologist
Division of Bioequivalence III
Office of Bioequivalence (OB) | OGD | CDER

10:00 – 10:15 am Break

10:15 – 10:20 am Welcome Back
Kori Adair, PharmD

10:20 – 10:35 am Bioequivalence Strategies for Chewable Tablets: Regulatory Considerations
Hye Lim Lim, PharmD
Visiting Associate
DTP II | ORS | OGD | CDER

10:35 – 10:45 am Risk Assessment and Navigating the Regulatory Landscape for Immediate-Release Drug-Coated Sphere Formulations
Wen Cheng Yang, MD
Senior Staff Fellow
DTP II | ORS | OGD | CDER

10:45 – 10:55 am Dose Selection Consideration for Pharmacokinetic Bioequivalence Studies of Oral Suspension Products
Duyen Nguyen, PharmD
Staff Fellow
DTP II | ORS | OGD | CDER

10:55 – 11:05 am Scientific and Regulatory Considerations for Sublingual Products
Wei-Jhe Sun, PhD
Senior Staff Fellow
DTP II | ORS | OGD | CDER

11:05 – 11:20 am Bioequivalence Strategies for Orally Disintegrating Tablets: Regulatory Considerations
Heather Boyce, PhD
Lead Pharmacokineticist
DTP II | ORS | OGD | CDER

11:20 – 11:40 am In Vitro Feeding Tube Studies: Scientific and Regulatory Perspectives

Shamema Nasrin, PhD
Contractor
DTP II | ORS | OGD | CDER

Geng Tian, PhD
Research Officer
Division of Pharmaceutical Quality Research VI
Office of Pharmaceutical Quality Research
OPQ | CDER

11:40 – 12:20 pm Question and Answer Session

Moderator:
Jihong Shon, MD, PhD

Hye Lim Lim, PharmD
Wen Cheng Yang, MD
Duyen Nguyen, PharmD
Wei-Jhe Sun, PhD
Heather Boyce, PhD
Shamema Nasrin, PhD
Geng Tian, PhD

and joined by:
Xiaojian Jiang, PhD
Deputy Division Director
Division of Bioequivalence II
OB | OGD | CDER

12:20 – 12:30 pm Closing Remarks

Myong-Jin Kim, PharmD
Division Director
DTP II | ORS | OGD | CDER