



CDER Small Business & Industry Assistance  
**Advancing Generic Drug Development (AGDD):  
Bioequivalence Challenges for Patient-Centric Oral Formulations**

June 11, 2026



# 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  
**Karen Li, PharmD**  
*Pharmacologist*  
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, PharmD**  
**Fang Wu, PhD**
- and joined by:  
**Meirong Hao, PhD**  
*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 Granules and Pellets PSGs  
**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

**Geng Tian, PhD**

*Research Officer*

Division of Pharmaceutical Quality Research VI

Office of Pharmaceutical Quality Research

OPQ | CDER

**Shamema Nasrin, PhD**

*Research Scientist*

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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*

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