DAY ONE: Tuesday, September 21, 2021

8:30 – 8:45
Welcome
Brenda Stodart, PharmD, BCGP, RAC
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

8:45 – 9:00
Keynote
Janet Woodcock, MD
Acting Commissioner of Food and Drugs
Food and Drug Administration

Your SBIA Hosts for Day One
Renu Lal, PharmD
LCDR, USPHS, Pharmacist
SBIA | DDI | OCOMM | CDER

Forest "Ray" Ford, Jr., PharmD
CAPT, USPHS, Pharmacist
SBIA | DDI | OCOMM | CDER

For files and resources, please visit
The Event Page on SBAIevents.com

Add Event to Your Calendar

AGENDA
All times are Eastern (EDT UTC-4)
View Start Time on World Clock
### DAY ONE: Tuesday, September 21, 2021

**Session 1: COVID-19 Impact on Generic Drug Regulation and Evaluation**

Session Leads: Liang Zhao, PhD (Division of Quantitative Methods & Modeling (DQMM) | Office of Research and Standards (ORS) | Office of Generics Drugs (OGD) | CDER) and Bing Li, PhD (Office of Bioequivalence (OB) | OGD | CDER)

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<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
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| 9:00 – 9:20 | Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency | Mitchell Frost, MD  
  *Acting Deputy Director*  
  Division of Therapeutic Performance II (DTP II)  
  ORS | OGD | CDER |
| 9:20 – 9:40 | Alternative Bioequivalence Approaches for Data Analysis Due to COVID-19 Related Study Interruptions | Yuqing Gong, PhD  
  *Pharmacologist*  
  DQMM | ORS | OGD | CDER |
| 9:40 – 10:00 | Quality Consideration in the Development of FDA Guidance “Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency” | Gloria Huang, PhD  
  *Lead Chemist*  
  Division of Liquid-Based Products II (DLBP II)  
  Office of Lifecycle Drug Products (OLDP)  
  Office of Pharmaceutical Quality (OPQ) | CDER |
| 10:00 – 10:20 | Applications and Lessons Learned for Conducting Adaptive Designs in Generic Drug Development | Kairui (Kevin) Feng, PhD  
  *Staff Fellow*  
  DQMM | ORS | OGD | CDER |
| 10:20 – 10:50 | Session 1: Q&A Panel | Mitchell Frost, Yuqing Gong, Gloria Huang, Kairui (Kevin) Feng, and Kimberly Witzmann, MD  
  *Acting Director*  
  Division of Clinical Review (DCR)  
  *Deputy Director*  
  Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER  
  Stella C. Grosser, PhD  
  *Director*  
  Division of Biometrics VIII  
  Office of Biostatistics (OB)  
  Office of Translational Sciences (OTS) | CDER |
| 10:50 - 11:05: BREAK | | |
### DAY ONE: Tuesday, September 21, 2021

#### Session 2: Considerations in Assessing Generic Drug Products of Oral Dosage Forms

Session Leads: Wei-Jhe Sun, PhD (Division of Bioequivalence | ORS | OGD | CDER), Fang Wu, PhD (DQMM | ORS | OGD | CDER), and Rong Wang, PhD (Division of Biometrics I (DB I) | OB | OGD | CDER)

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<tr>
<th>Time</th>
<th>Presentation</th>
<th>Speaker</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>11:05 - 11:25</td>
<td>Nasal Pharmacokinetic Study of Abuse-Deterrent Oxycodone HCl ER Products Following Insufflation of Physically Manipulated Products</td>
<td>Saeid Raofi, MS&lt;br&gt;Pharmacologist</td>
<td>DTP II</td>
</tr>
<tr>
<td>11:25 – 11:45</td>
<td>Advancement in the In-Vitro Evaluation of Abuse-Deterrent Formulations for Opioid Analgesics: Research and Assessment Perspectives</td>
<td>Manar Al-Ghabeish, PhD&lt;br&gt;Staff Fellow</td>
<td>Division of Product Quality Research (DPQR)&lt;br&gt;OTR</td>
</tr>
<tr>
<td>11:45 – 12:05</td>
<td>Physiological Based Pharmacokinetic Modeling and Simulation Absorption Modeling and Virtual Bioequivalence to Support Generic Drug Development and Regulatory Decision Making for Oral Products</td>
<td>Fang Wu, PhD&lt;br&gt;Acting Team Lead</td>
<td>DQMM</td>
</tr>
<tr>
<td>12:05 – 12:25</td>
<td>Safety Assessment of Flavors in Generic Drug Products</td>
<td>Melanie Mueller, PharmD, PhD&lt;br&gt;Team Lead</td>
<td>Division of Pharmacology/Toxicology Review (DPTR)&lt;br&gt;OSCE</td>
</tr>
<tr>
<td>12:25 – 12:55</td>
<td>Session 2: Q&amp;A Panel</td>
<td>Saeid Raofi, Manar Al-Ghabeish, Fang Wu, Melanie Mueller, and Xiaoming Xu, PhD&lt;br&gt;Supervisory Chemist</td>
<td>DPQR</td>
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<td>Heather Boyce, PhD&lt;br&gt;Acting Team Lead</td>
<td>DTP II</td>
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<th>Time</th>
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<tr>
<td>12:55 – 1:30 PM</td>
<td>LUNCH BREAK</td>
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</table>
### DAY ONE: Tuesday, September 21, 2021

**Session 3: Complex Generics: Complex Injectables, Ophthalmic and Otic Products, Part 1**

Session Leads: **Pahala Simamora, PhD** (DLBP II | OLDP | OPQ | CDER) and **Darby Kozak, PhD** (DTP I | ORS | OGD | CDER)

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<th>Time</th>
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<tbody>
<tr>
<td>1:30 - 1:50</td>
<td>Advances in Iron Colloid Products: Product-Specific Guidance (PSG) Discussion</td>
<td>Wenlei Jiang, PhD</td>
<td>Senior Science Advisor, Immediate Office (IO), ORS</td>
</tr>
<tr>
<td>1:50 – 2:10</td>
<td>Advances in Iron Colloid Products: Quality Considerations When Conducting Comparability Studies</td>
<td>Yiwei Li, PhD</td>
<td>Branch Chief, Division of Pharmaceutical Manufacturing IV (DPMAIV), Office of Pharmaceutical Manufacturing Assessment (OPMA)</td>
</tr>
<tr>
<td>2:10 – 2:30</td>
<td>Injectable Suspensions: Tools and Methods Bridging the In Vivo and In Vitro Gap</td>
<td>Bin Qin, PhD</td>
<td>Staff Fellow, DTP I</td>
</tr>
</tbody>
</table>
| 3:00 – 3:30 | Session 3, Part 1: Q&A Panel | Wenlei Jiang, Yiwei Li, Bin Qin, and Bruce Lerman, PhD | Lead Pharmacologist, DB I | OB | OGD | CDER  
|              |              | Darby Kozak, PhD         | Deputy Director, DTP I | ORS | OGD | CDER |

3:00 – 3:15 PM: BREAK
**DAY ONE: Tuesday, September 21, 2021**

**Session 3: Complex Generics: Complex Injectables, Ophthalmic and Otic Products, Part 2**

Session Leads: **Pahala Simamora, PhD** (DLBP II | OLDP | OPQ | CDER) and **Darby Kozak, PhD** (DTP I | ORS | OGD | CDER)

<table>
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<tr>
<th>Time</th>
<th>Session</th>
<th>Title</th>
<th>Speaker</th>
<th>Affiliations</th>
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</table>
| 3:15 – 3:35|         | **Challenges in the Approval of Complex Otic and Ophthalmic Generic Products: Bioequivalence Perspectives** | Chunsheng Zhao, PhD     | Bioequivalence Reviewer  
Division of Bioequivalence III (DB III)  
OB | OGD | CDER |
| 3:35 - 3:55|         | **Challenges in the Approval of Complex Otic & Ophthalmic Generic Products: Quality Perspectives** | Poonam Chopra, PhD      | Review Chemist  
DLBP II | OLDP | OPQ | CDER |
| 3:55 – 4:15|         | **Physiological Based Pharmacokinetic Modeling and Simulation to Support Generic Ophthalmic Drug Product Development and Regulatory Decision Making** | Mingliang Tan, PhD      | Staff Fellow  
DQMM | ORS | OGD | CDER |
| 4:15 – 4:45|         | **Session 3, Part 2: Q&A Panel**                                    | Chunsheng Zhao, Poonam Chopra, Mingliang Tan, Yan Wang, and Asif Rasheed, PhD |  
Asif Rasheed, PhD  
Senior Chemist  
DLBPI | OLDP | OPQ | CDER  
Kai Kwok, PhD  
Senior Pharmaceutical Quality Assessor  
DLBP II | OLDP | OPQ | CDER |
| 4:45 – 4:50|         | **Day 1, Closing Remarks**                                           | Lei Zhang, PhD          | Deputy Director  
ORS | OGD | CDER |
|            |         | **4:50 PM: DAY ONE ADJOURN**                                         |                          |                                                 |
DAY TWO: Wednesday, September 22, 2021

8:30 – 8:40
Day Two Welcome

Renu Lal, PharmD
LCDR, USPHS
Pharmacist
SBIA | DDI | OCOMM | CDER

Your SBIA Hosts for Day Two
Renu Lal, PharmD
LCDR, USPHS, Pharmacist
SBIA | DDI | OCOMM | CDER

Forest "Ray" Ford, Jr., PharmD
CAPT, USPHS, Pharmacist
SBIA | DDI | OCOMM | CDER

Session 4: Cutting Edge Science in Complex Generics
Session Leads: Lei Zhang, PhD (ORS | OGD | CDER) and Lucy Fang, PhD (DQMM | ORS | OGD | CDER)

8:40 – 9:00
Utility of Artificial Intelligence to Facilitate the Development and Regulatory Assessment of Complex Generic Drugs

Meng Hu, PhD
Acting Team Lead
DQMM | ORS | OGD | CDER

9:00 – 9:20
Model-Integrated Evidence for Bioequivalence Assessment of Complex Generic Drugs

Miyoung Yoon, PhD
Acting Team Lead
DQMM | ORS | OGD | CDER

9:20 – 9:40
Scanning Electron Cryomicroscopy (Cryosem) for Characterization of Complex Drug Products

Huzeyfe Yilmaz, PhD
Staff Fellow
Division of Complex Drug Analysis (DCDA)
OTR | OPQ | CDER

9:40 – 10:00
Advanced Imaging and Data Analysis to Support Compositional Structure Similarity of Polymeric Formulations

Yan Wang, PhD
Acting Team Lead
DTP I | ORS | OGD | CDER
**DAY TWO: Wednesday, September 22, 2021**

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<tr>
<th>Time</th>
<th>Session 4: Q&amp;A Panel</th>
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<tr>
<td>10:00 – 10:30</td>
<td>Meng Hu, Miyoung Yoon, Huzeyfe Yilmaz, Yan Wang, and Robert Lionberger, PhD (Director)</td>
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<td>Daniel Willett, PhD (Chemist)</td>
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<tr>
<th>Time</th>
<th>10:30 – 10:45 AM: BREAK</th>
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**Session 5: Complex Generics: Nasal and Inhalation Products**

Session Leads: Changning Guo, PhD (DCDA | OTR | OPQ | CDER), Michael Spagnola, MD (Division of Clinical Safety and Surveillance (DCSS) | OSCE | OGD | CDER), and Sneha Dhapare, PhD (DTP I | ORS | OGD | CDER)

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<tr>
<th>Time</th>
<th>Session Details</th>
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<tr>
<td>10:45 – 11:05</td>
<td>Product-Specific Considerations for Alternative Bioequivalence (BE) Approaches to Comparative Clinical Endpoint BE Studies</td>
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<td>Susan Boc, PhD (Scientific Researcher)</td>
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<tr>
<td>11:05 – 11:25</td>
<td>Approaches for studies interrupted due to COVID-19 for Nasal and Inhalation Products</td>
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<tr>
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<td>Vipra Kundoor, PhD (Pharmacologist)</td>
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<tr>
<td>11:25 – 11:45</td>
<td>Demonstrating Bioequivalence with Inhalation Spray Drug Products</td>
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<td>Sneha Dhapare, PhD (Visiting Associate)</td>
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<td>11:45 – 12:05</td>
<td>Comparative Analyses for Generic Oral Inhalers</td>
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<td>Michael Spagnola, MD (Lead Physician)</td>
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### DAY TWO: Wednesday, September 22, 2021

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<tr>
<th>Time</th>
<th>Session</th>
<th>Title</th>
<th>Speakers</th>
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| 12:05 – 12:35| Session 5: Q&A Panel | Susan Boc, Vipra Kundoor, Sneha Dhapare, Michael Spagnola, and Bryan Newman, PhD  
Acting Team Lead  
DTP I | ORS | OGD | CDER  
Changning Guo, PhD  
Supervisory Chemist  
DCDA | OTR | OPQ | CDER  
Bing Cai, PhD  
Director  
DLBP | OLPD | OPQ | CDER |
| 12:35 - 1:10: | LUNCH BREAK | | |

### Session 6: Complex Generics: Topical Products, Part 1

**Session Leads:** Ying Fan, PhD (DCR | OSCE | OGD | CDER), and Tannaz Ramezanli, PhD, PharmD (DTP I | ORS | OGD | CDER)

<table>
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<tr>
<th>Time</th>
<th>Title</th>
<th>Speakers</th>
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| 1:10 – 1:30  | “No Difference” Standard vs. Q1|Q2 Sameness for Topical Drug Products  
Megan Kelchen, PhD  
Pharmacologist  
DTP I | ORS | OGD | CDER |
| 1:30 – 1:50  | Use of Q3 Characterization Tests for Topical Semisolid Drug Products  
Sam Raney, PhD  
Associate Director for Science  
IO | ORS | OGD | CDER |
| 1:50 – 2:10  | Recent Research Related to Q3 Characterization of Topical Products Containing Porous Microparticles  
Ahmed Zidan, PhD  
Senior Pharmacologist  
DPQR | OTR | OPQ | CDER |
| 2:10 – 2:40  | Challenges and Considerations with Model-based Virtual Bioequivalence Assessments for Generic Dermatological Products  
Eleftheria Tsakalozou, PhD  
Staff Fellow  
DQMM | ORS | OGD | CDER  
Khondoker Alam, PhD  
Staff Fellow  
DQMM | ORS | OGD | CDER |

**Speaker Biographies**

All times shown are Eastern (EDT UTC-4)
DAY TWO: Wednesday, September 22, 2021

2:40 – 3:10

**Session 6, Part 1: Q&A Panel**

Megan Kelchen, Sam Raney, Ahmed Zidan, Khondoker Alam, Eleftheria Tsakalozou, and Markham Luke, MD, PhD

*Director*

DTP I | ORS | OGD | CDER

3:10 – 3:20 PM: BREAK

**Session 6: Complex Generics: Topical Products, Part 2**

Session Leads: **Ying Fan, PhD** (DCR | OSCE | OGD | CDER), and **Tannaz Ramezanli, PhD, PharmD** (DTP I | ORS | OGD | CDER)

3:20 – 3:40

**Common Issues Identified in In-vitro Release Test (IVRT) and In-vitro Permeation Test (IVPT) Studies Submitted in ANDA to Support Bioequivalence for Topical Products**

**Josephine Aimiuwu, PhD**

*Pharmacologist*

DB II | OB | OGD | CDER

3:40 – 4:00

**Theoretical Principles and Best Practices: In Vitro Release Test**

**Tannaz Ramezanli, PhD, PharmD**

*Pharmacologist*

DTP I | ORS | OGD | CDER

4:00 – 4:20

**Theoretical Principles and Best Practices: In Vitro Permeation Test**

**Priyanka Ghosh, PhD**

*Acting Team Lead*

DTP I | ORS | OGD | CDER

4:20 – 4:50

**Session 6, Part 2: Q&A Panel**

Josephine Aimiuwu, Tannaz Ramezanli, Priyanka Ghosh, Markham Luke, and Sam Raney

4:50 – 5:00

**Closing Remarks**

**Robert Lionberger, PhD**

*Director*

ORS | OGD | CDER

5:00: ADJOURN WORKSHOP

Speaker Biographies