Version 3 – Updated July 31, 2023

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AGENDA

All times are Eastern (UTC-5)
View Start Time on World Clock

DAY ONE: Wednesday, September 13, 2023

9:00 – 9:15

Welcome

Brenda Stodart, PharmD, MS, BCGP, RAC
Captain, United States Public Health Service
Director, Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

9:15 – 9:30

Keynote

Robert Califf, MD (Invited)
Commissioner of Food and Drugs
Food and Drug Administration

Your SBIA Hosts for Day One

Forest "Ray" Ford, PharmD, BCPS
CAPT, USPHS, *Pharmacist*
DDI | OCOMM | CDER

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

DAY ONE: Wednesday, September 13, 2023

Session 1: Noteworthy Guidances and Generic Approvals for Topical and Transdermal Products

Session Leads: **Darby Kozak, PhD,** *Deputy Director*, Division of Therapeutic Performance I (DTP I) | Office of Research and Standards (ORS) | Office of Generic Drugs (OGD) | Center for Drug Evaluation and Research (CDER) and **Ahmed Zidan, PhD,** *Senior Staff Fellow*, Division of Product Quality Research (DPQR) | Office of Testing and Research (OTR) | Office of Pharmaceutical Quality (OPQ) | CDER

9:30 – 10:00

General Guidances Related to Characterization-Based Bioequivalence Approaches for Topical Products

Priyanka Ghosh, PhD
Lead Pharmacologist
DTP I | ORS | OGD | CDER

Hiren Patel, PhD
Senior Staff Fellow
Division of Bioequivalence II (DB II)
Office of Bioequivalence (OB) | OGD | CDER

10:00 – 10:20

An Overview of the Current Product-Specific Guidances for Topical Products

Megan Kelchen, PhD
Senior Pharmacologist
DTP I | ORS | OGD | CDER

10:20 – 10:40

How Research Supports Product-Specific Guidances for Topical Products

Ahmed Zidan, PhD
Senior Staff Fellow
DPQR | OTR | OPQ | CDER

10:40 – 10:50: BREAK

All times shown are Eastern (UTC-5)

DAY ONE: Wednesday, September 13, 2023

10:50 – 11:10

Overview and Changes to Guidance for Industry: Topical Dermatology Corticosteroids In Vivo Bioequivalence

Ke Ren, PhD
Deputy Division Director
Division of Bioequivalence III (DB III) | OB | OGD | CDER

11:10 – 11:30

ANDA Challenges Related to Vasoconstrictor Studies

Kairui (Kevin) Feng, PhD
Senior Chemical Engineer
Division of Quantitative Methods and Modeling (DQMM) | ORS | OGD | CDER

11:30 – 12:15

Session 1: Q&A Panel

Priyanka Ghosh, Hiren Patel, PhD, Megan Kelchen, Ahmed Zidan, Ke Ren, Kairui (Kevin) Feng, and

Markham C. Luke, MD, PhD
Division Director, DTP I | ORS | OGD | CDER

Sam Raney, PhD
Associate Director for Science, ORS | OGD | CDER

Pahala Simamora, PhD
Division Director, DLBP II | OLDP | OPQ | CDER

Rong Wang, PharmD, PhD
Associate Director, DB I | OB | OGD | CDER

12:15 – 1:00 PM: LUNCH BREAK

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DAY ONE: Wednesday, September 13, 2023

Session 2: Noteworthy Guidances for Nasal Suspension and Inhalation Products

Session Leads: **Darby Kozak, PhD,** *Deputy Director*, DTP I | ORS | OGD | CDER and **Ahmed Zidan, PhD,** *Senior Staff Fellow*, DPQR | OTR | OPQ | CDER

1:00 – 1:20

Complex Nasal Suspension PSG: Utilization of Newly Recommended In Vitro Only Bioequivalence Option

Susan Boc, PhD
Pharmacokineticist
DTP I | ORS | OGD | CDER

1:20 – 1:40

Complex Nasal Suspension: Utilization of In Silico PK Studies to Support Development and Approval

Ross Walenga, PhD
Senior Chemical Engineer
DQMM | ORS | OGD | CDER

1:40 – 2:00

Loxapine Inhalation Powder: OTR Research Conducted to Inform the PSG Recommendations

Nathan Reed, PhD
Chemist
DCDA B2, OTR, OPQ, CDER

Elizabeth Bielski, PhD
Senior Pharmacologist
DTP I, ORS, OGD, CDER

2:00 – 2:30

Session 2: Q&A Panel

Susan Boc, Ross Walenga, Nathan Reed, Elizabeth Bielski, and

Vipra Kundoor, PhD
Pharmacologist, DB I | OB | OGD | CDER

Mai Tu, PhD
Chemist, LBB4 | DLBP II | OLDP | OPQ | CDER

Ahmed Zidan, PhD
Senior Staff Fellow, DPQR | OTR | OPQ | CDER

2:30 – 2:40 PM: BREAK

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DAY ONE: Wednesday, September 13, 2023

Session 3: Noteworthy Guidances for Injectable Products

Session Leads: **Cameron Smith, PhD**, *Branch Chief*, DLBP I | OLDP | OPQ | CDER and **Yan Wang, PhD**, *Lead Pharmacologist*, DTP I | ORS | OGD | CDER

2:40 – 2:55

In Vitro Approaches for Injectable Suspension Products: Medroxyprogesterone Acetate & Triamcinolone Acetate

Qiangnan Zhang, PhD
Staff Fellow
DTP I | ORS | OGD | CDER

2:55 – 3:10

Risk-based PSG Recommendations for Comparative Immunogenicity and Impurity Profile Assessment

Eric Pang, PhD
Senior Chemist
DTP I | ORS | OGD | CDER

3:10 – 3:30

Session 3: Q&A Panel

Qiangnan Zhang, Eric Pang, and

Dapeng Cui, PhD
Lead Pharmacologist, DB I | OB | OGD | CDER

Cameron Smith, PhD
Branch Chief, DLBP I | OLDP | OPQ | CDER

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DAY ONE: Wednesday, September 13, 2023

Session 4: Noteworthy Complex Generic Drug Approvals: Multiphase Systems

Session Leads: **Brock Roughton, PhD**, *Branch Chief*, DLBP II | OLDP | OPQ | CDER and **Ke Ren, PhD**, *Deputy Division Director*, DB III | OB | OGD | CDER

3:30 – 3:50

Cyclosporine & Difluprednate Ophthalmic Emulsions

Qiuxi Fan, PhD
Pharmaceutical Scientist
DLBP II | OLDP | OPQ | CDER

Yoriko Harigaya, PharmD
Senior Staff Fellow
DB II | OB | OGD | CDER

3:50 – 4:10

Amphotericin B Liposome: Changes Identified

Bin Qin, PhD
Senior Chemist
DTP I | ORS | OGD | CDER

4:10 – 4:25

Phytonadione – Self-Assembled System & Thermodynamics Systems

William Smith, PhD
Research Scientist
DPQR | OTR | OPQ | CDER

4:25 – 4:55

Session 4: Q&A Panel

Qiuxi Fan, Yoriko Harigaya, Bin Qin, William Smith, and

John Jiang, PhD
Chemist, DLBP II | OLDP | OPQ | CDER

Hee Chung, PhD
Lead Pharmacologist, DB I | OB | OGD | CDER

Khondoker Alam, PhD
Senior Pharmacologist, DQMM | ORS | OGD | CDER

Xiaoming Xu, PhD
Supervisory Chemist, DPQR | OTR | OPQ | CDER

4:55 – 5:00

Day One Closing Remarks

Lei Zhang, PhD
Deputy Director
ORS | OGD | CDER

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DAY TWO: Thursday, September 14, 2023

9:00 – 9:15

Day Two SBIA Overview

Forest "Ray" Ford, PharmD, BCPS
CAPT, USPHS
DDI | OCOMM | CDER

Session 5: Noteworthy Complex Generic Drug Approvals: Orally Inhaled Products

Session Leads: **Lanyan (Lucy) Fang, PhD**, *Deputy Division Director*, DQMM | ORS | OGD | CDER and **Michael Spagnola, MD**, *Lead Physician*, Division of Clinical Safety and Surveillance (DCSS) | Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER

9:15 – 9:30

Innovative Technology: Particle Image Velocimetry (PIV) and High-Speed Imaging to Support Approval of Generic Orally Inhaled Drug Products

Steven Chopski, PhD
Staff Fellow
DQMM | ORS | OGD | CDER

9:30 – 9:45

First Generic Drug Approval: Budesonide & Formoterol Fumarate Dihydrate Inhalation Aerosol (RLD: Symbicort): A Bioequivalence Perspective

Zhen Xu, PhD
Staff Fellow
DB III | OB | OGD | CDER

9:45 – 10:00

First Generic Drug Approval: Budesonide & Formoterol Fumarate Dihydrate Inhalation Aerosol (RLD: Symbicort): A Quality Perspective

Fang Yuan, PhD
Senior Chemist
IO | OLDP | OPQ | CDER

10:00 – 10:15

Post-Approval Impact of Generic Fluticasone Propionate & Salmeterol Inhalation Powder

Andrew Clerman, MD, PhD
Senior Physician
Division of Therapeutic Performance I (DTP I)
ORS | OGD | CDER

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DAY TWO: Thursday, September 14, 2023

10:15 – 10:55

Session 5: Q&A Panel

Steven Chopski, Zhen Xu, Fang Yuan, Andrew Clerman, and

Srinivas Behara, PhD
Chemist, Division of Immediate and Modified Release Products III (DIMRP III)
OLDP | OPQ | CDER

Tian Ma, PhD
Senior Staff Fellow, DB I | OB | OGD | CDER

Elizabeth Bielski, PhD
Senior Pharmacologist, DTP I | ORS | OGD | CDER

10:55 – 11:05 AM: BREAK

Session 6: Noteworthy Complex Generic Drug Approvals: Oral Locally Acting & Oral Suspension Drug Products

Session Leads: **Brock Roughton, PhD**, *Branch Chief*, DLBP II | OLDP | OPQ | CDER and **Ke Ren, PhD**, *Deputy Division Director*, DB III | OB | OGD | CDER

11:05 – 11:25

In Vitro Binding Studies for Bioequivalence Demonstration

Wei-Jhe Sun, PhD
Senior Staff Fellow
DTP II, ORS, OGD, CDER

11:25 – 11:45

Q1/Q2 Recommendation (Sucralfate)

Manar Al-Ghabeish, PhD
Staff Fellow
DTP II | ORS | OGD | CDER

11:45 – 12:05

Non-Q2 Sucralfate Suspension Approval

Suman Dandamudi, PhD
Senior Pharmacologist
DB III | OB | OGD | CDER

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DAY TWO: Thursday, September 14, 2023

12:05 – 12:35

Session 6: Q&A Panel

Wei-Jhe Sun, Manar Al-Ghabeish, Suman Dandamudi, and

Alicia Hoover, PhD
Supervisory Chemist, Division of Pharmaceutical Analysis (DPA) | OTR | OPQ | CDER

Fang Wu, PhD
Senior Pharmacologist, DQMM | ORS | OGD | CDER

Hongfei Zhou, PhD
Senior Pharmacologist, DB III | OB | OGD | CDER

12:35 – 1:35: LUNCH BREAK

Session 7: Enhanced Processes, Research, and Assessment Tools to Support Generic Drug Product Development

Session Leads: **Lanyan (Lucy) Fang, PhD**, *Deputy Division Director*, DQMM | ORS | OGD | CDER and **Michael Spagnola, MD**, *Lead Physician*, Division of Clinical Safety and Surveillance (DCSS) | Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER

1:35 – 1:50

GDUFA Research Program: Research Priorities to Support Generic Drug Development

Sam Raney, PhD
Associate Director for Science
ORS | OGD | CDER

1:50 – 2:05

Identify Research Needs and PSG Development for Complex Products

Xiaoming Xu, PhD
Division Director
DPQR | OTR | OPQ | CDER

2:05 – 2:20

Enhance Communication in Using Modeling Approaches in ANDAs

Liang Zhao, PhD
Division Director
DQMM | ORS | OGD | CDER

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DAY TWO: Thursday, September 14, 2023

2:20 – 2:50

Session 7: Q&A Panel

Sam Raney, Xiaoming Xu, Liang Zhao, and

Darby Kozak, PhD
Deputy Division Director | DTP I | ORS | OGD | CDER

Robert Lionberger, PhD
Director | ORS | OGD | CDER

Zhen Zhang, PhD
Master Pharmacologist | DB I | OB | OGD | CDER

2:50 – 3:00 PM: BREAK

Session 8: Global Collaboration to Support Efficient Generic Product Development & Regulatory Assessment

Session Leads: **Heather Boyce, PhD**, *Lead Pharmacokineticist*, DTP II | ORS | OGD | CDER and **Diana Vivian, PhD**, *Associate Director*, DB II | OB | OGD | CDER

3:00 – 3:15

Supporting the First Harmonized Bioequivalence Guideline under ICH -Considerations for Future Implementation

Nilufer Tampal, PhD
Associate Director for Scientific Quality
OB | OGD | CDER

3:15 – 3:30

FDA-EMA Parallel Scientific Advice Pilot Program for Complex Generic/Hybrid Drug Products

Lei Zhang, PhD
Deputy Director
ORS | OGD | CDER

3:30 – 3:45

The Generic Drug Cluster Program and the Path to Global Harmonization

Sarah Ibrahim, PhD
Associate Director for Global Affairs
OGD | CDER

3:45 - 4:00

Data Reliability – Inspection, Global Collaboration

Brian Folian, JD, MS
Deputy Director
Office of Study Integrity and Surveillance (OSIS)
Office of Translational Sciences (OTS) | CDER

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DAY TWO: Thursday, September 14, 2023

4:00 – 4:40

Session 8: Q&A Panel

Nilufer Tampal, Lei Zhang, Sarah Ibrahim, Brian Folian, and

Wenlei Jiang, PhD
Senior Advisor for Innovation and Strategic Outreach, ORS | OGD | CDER

Xiaojian Jiang, PhD
Deputy Division Director, DB II | OB | OGD | CDER

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

4:40 – 4:50

Closing Remarks

Robert Lionberger, PhD
Director
ORS | OGD | CDER

4:50: WORKSHOP ADJOURN

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List of Acronyms Used in This Document:

Board Certified Geriatric Pharmacist (BCGP)

Board Certified Pharmacotherapy Specialists (BCPS)

Captain (CAPT)

Center for Drug Evaluation and Research (CDER)

Division of Bioequivalence I (DB I)

Division of Bioequivalence II (DB II)

Division of Bioequivalence III (DB III)

Division of Biotechnology Review and Research III (DBRR III)

Division of Clinical Safety and Surveillance (DCSS)

Division of Complex Drug Analysis (DCDA)

Division of Drug Information (DDI)

Division of Immediate and Modified Release Products III (DIMRP III)

Division of Liquid-Based Products I (DLBP I)

Division of Liquid-Based Products II (DLBP II)

Division of Product Quality Research (DQPR)

Division of Quantitative Methods & Modeling (DQMM)

Division of Therapeutic Performance I (DTP I)

Division of Therapeutic Performance II (DTP II)

Doctor of Medicine (MD)

Doctor of Pharmacy (PharmD)

Doctor of Philosophy (PhD)

Food and Drug Administration (FDA)

Lieutenant Commander (LCDR)

Liquid-Based Branch 4 (LBB 4)

Master of Science (MS)

Office of Bioequivalence (OB)

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Office of Safety & Clinical Evaluation (OSCE)

Office of Study Integrity and Surveillance (OSIS)

Office of Testing & Research (OTR)

Office of Translational Sciences (OTS)

Regulatory Affairs Certification (RAC)

Small Business, and Industry Assistance (SBIA)

United States Public Health Service (USPHS)