Version 14 – Updated September 26, 2020

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AGENDA

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View the Speakers' Biographies

DAY ONE: Tuesday, September 29, 2020

8:00 – 8:15

Welcome

Brenda Stodart
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

8:15 – 8:30

Keynote

Stephen M. Hahn
Commissioner of Food and Drugs
Food and Drug Administration

Your SBIA Hosts for Day One

Forest "Ray" Ford, Jr.
CAPT, USPHS, *Pharmacist*
DDI | OCOMM

Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

8:30 – 9:10

Update on GDUFA Science and Research

Robert Lionberger
Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER

DAY ONE: Tuesday, September 29, 2020

Session 1: Method Development / Validations for Non-traditional Analytical Methods

Session Leads: **Darby Kozak** (ORS | OGD) and **Bing Cai** (Office of Lifecycle Drug Products (OLDP) | Office of Pharmaceutical Quality (OPQ))

Session 1, Topic 1: Complex Active Pharmaceutical Ingredients Including Peptide Products

9:10 – 9:30

March 2020 Transition Under the BPCI Act: Impact on Generics

This presentation will discuss the March 23, 2020 transition under the Biologics Price Competition and Innovation Act of 2009 as it relates to generic drugs. It will describe FDA's interpretation of the term "protein" in the amended definition of "biological product," provide examples of approved NDAs for biological products that transitioned to BLAs, and provide examples of products that remain NDAs and thus continue to serve as potential reference list drugs (RLDs) for ANDA submissions.

Mindy Ehrenfried
Office of Generic Drug Policy (OGDP)
OGD | CDER

9:30 – 9:50

Related Impurities Assessment Considerations for APIs in the Generic Complex Peptide Products

This presentation will outline the specification considerations for peptide-related impurities in Active Pharmaceutical Ingredients (APIs) of the generic complex peptide drugs as the ICH guideline (Q3A) does not apply to these generic peptide drug substances. Discussion includes current thinking and recommendations.

Manivannan Ethirajan
Office of New Drug Products (ONDP)
OPQ | CDER

9:50 – 10:10

Non-clinical Evaluation of Immunogenicity Risk of Generic Complex Peptide Products

This presentation will discuss some of the available in vitro and in silico methods for conducting comparative immunogenicity assessment for certain complex peptide drug products and their impurities, as per the recommendations in FDA's draft guidance on *ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin*.

Eric Pang
ORS | OGD | CDER

10:10 – 10:30

Session 1, Topic 1: Q&A Panel

Mindy Ehrenfried, Manivannan Ethirajan, Eric Pang, and Daniela Verthelyi (Office of Biotechnology Products (OBP) | OPQ)

10:30 - 10:45: BREAK

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DAY ONE: Tuesday, September 29, 2020

Session 1, Topic 2: Advanced Analytical and Statistical Methods for Assessing Particle Size Distributions

10:45 - 11:05

Developing and Validating Advanced Microscopy Methods for Supporting Complex Product Equivalence

This presentation will discuss new microscopy methods that provide high-resolution analysis of particle morphology and can be used in combination of spectral analysis methods to characterize and discriminate between different chemical species of particles or distribution of drug particulates in complex drug products.

Changning Guo
Office of Testing and Research (OTR)
OPQ | CDER

11:05 – 11:25

Developing and Validating Commonly Employed Particle Sizing Methods to Support Bioequivalence (BE) and Product Quality

This presentation will discuss common issues and considerations in the development and validation of an analytical method for particle size characterization.

Xiaoming Xu
OTR | OPQ | CDER

11:25 – 11:45

Quantitative Methods for Determining Equivalence of Particle Size Distributions

This presentation will discuss quantitative methods for comparing particle size distributions to demonstrate equivalence. This includes the considerations and use of the appropriate descriptors for particle size histograms and the following statistical equivalence method, such as the Population Bioequivalence (PBE), under different scenarios (e.g., monomodal vs. complex distribution profile).

Meng Hu
ORS | OGD | CDER

11:45 – 12:05

Session 1, Topic 2: Q&A Panel

Changning Guo, Xiaoming Xu, and Meng Hu

12:05 - 1:05 PM: LUNCH BREAK

View the Speakers' Biographies

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DAY ONE: Tuesday, September 29, 2020

Session 1, Topic 3: Development and Validation Considerations for Drug Release and Permeation Testing of Complex Dosage Forms

1:05 - 1:25

Assessment of Complex Drug Product – Physicochemical Characteristics to Support In Vitro Bioequivalence Studies

This presentation will discuss common issues and challenges for assessment of physicochemical characteristics to support in vitro bioequivalence studies for complex ophthalmic drug.

Asif Rasheed
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER

1:25 - 1:45

In Vitro Release Testing for Complex Generics: A Bioequivalence Perspective

This presentation will discuss common issues and scientific considerations for the development and validation of an in vitro drug release testing method for supporting bioequivalence.

Yan Wang
ORS | OGD | CDER

1:45 – 2:05

In Vitro Bioequivalence Studies of Topical Drug Products: Challenges and Promises of In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT)

This presentation will highlight issues observed with IVRT and IVPT studies submitted in ANDAs to support bioequivalence of topical drug products. The presenter will discuss scientific challenges related to the development and validation of IVRT and IVPT methods along with data analysis. Practical considerations for the submission of detailed and well-organized information in ANDAs will be described.

Hiren Patel
Office of Bioequivalence (OB) | OGD
CDER

2:05 – 2:25

Session 1, Topic 3: Q&A Panel

Asif Rasheed, Yan Wang and Hiren Patel

2:25 - 2:40 PM: BREAK

View the Speakers' Biographies

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DAY ONE: Tuesday, September 29, 2020

Session 2: Excipient and Formulation Considerations

Session Leads: **Wenlei Jiang** (ORS | OGD) and **Ethan Stier** (OB | OGD)

2:40 – 3:00

Navigating Formulation Assessments: From General Q1/Q2 Inquiries to Supporting Complex Excipient Sameness

This presentation will discuss the general framework of what OGD considers in a qualitative (Q1) and quantitative (Q2) assessment request as well as common issues and considerations for industry to employ when making these requests. The talk will also include an overview of common supportive evidence that may be submitted to support equivalence of complex non-compendial excipients such as polymeric materials.

Darby Kozak
ORS | OGD | CDER

3:00 - 3:20

Calculating Maximum Daily Dose (MDD) for Orally Administered Drug Products

This presentation will discuss how to calculate the maximum daily dose (MDD) for oral dosage forms based on the reference listed drug labeling. This talk will also discuss common assessment issues encountered when evaluating the MDD.

Amanda Jones
OB | OGD | CDER

3:20 – 3:40

What's New in the Inactive Ingredient Database (IID)?

This presentation will provide an update on how the FDA fulfills its GDUFA II commitment to add maximum daily exposure (MDE) to the inactive ingredient database (IID), how the MDE is calculated, and how applicants should use the MDE to qualify excipients.

Susan Zuk
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER

3:40 – 4:00

Local Toxicity Considerations for Qualifying Excipients in Generic Drugs

This presentation will discuss how some dosage forms warrant safety justification of excipients for both local exposure at the site of administration and for systemic exposure. The presentation will discuss why it is important to address safety of excipients from both local and systemic exposure for these dosage forms. Several examples will be provided to illustrate how these cases can be justified.

Yongcheng Huang
OB | OGD | CDER

4:00 – 4:30

Session 2: Q&A Panel

Darby Kozak, Amanda Jones, Susan Zuk, and Yongcheng Huang

4:30 PM: DAY ONE ADJOURN

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DAY TWO: Wednesday, September 30, 2020

8:00 – 8:10

Day Two Overview

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

Your SBIA Hosts for Day Two

Forest "Ray" Ford, Jr.
CAPT, USPHS, *Pharmacist*
DDI | OCOMM

Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

Session 3: Future Directions, Emerging Technology, and Current Thinking on Alternative BE Approaches

Session Leads: **Andrew Babiskin** (ORS | OGD), **Sam Raney** (ORS | OGD) and **Bryan Newman** (ORS | OGD)

Session 3, Topic 1: Nasal & Inhalation Products

8:10 – 8:30

Advancements in In Vitro Studies for Alternative BE Approaches to Comparative Clinical Endpoint BE Studies

This presentation will discuss the Agency's current perspectives on comparative clinical endpoint BE studies with Orally Inhaled and Nasal Drug Products (OINDPs), as well as the Agency's efforts to address its challenges through alternative BE approaches. The alternative BE approaches recommended in recently posted product-specific guidances (PSGs) for solution-based Metered Dose Inhalers (MDIs) will be described, along with brief discussions on supporting data, critical study parameters, and the potential for expanding alternative BE approaches to more complex orally inhaled products.

Elizabeth Bielski
ORS | OGD | CDER

8:30 – 8:50

The Potential of Pharmacokinetic Bioequivalence (BE) Studies in Detecting Regional Deposition with Orally Inhaled Drug Products

This presentation will discuss the potential of, and challenges with, using PK BE studies as part of an alternative BE approach for assessing equivalence in regional lung deposition. The Agency's research efforts for investigating the sensitivity of PK BE studies in assessing regional lung deposition with a Dry Powder Inhaler (DPI) product will be described. In addition, this presentation will cover the lessons learned with the PK study, and the potential for including PK BE studies in alternative BE approach proposals for DPI products.

Liangfeng Han
ORS | OGD | CDER

DAY TWO: Wednesday, September 30, 2020

8:50 – 9:10

Bridging the Gap Between Regional Deposition and Systemic Pharmacokinetic Data of OINDPs with Modeling and Simulation

This presentation will discuss (1) Current knowledge gap between regional deposition and systemic PK data of Orally Inhaled and Nasal Drug Products (OINDPs) for inference of local lung tissue PK, (2) Available modeling and simulation techniques as well as utility and limitations for each technique with respect to predicting various aspects of OINDP delivery, (3) Modeling strategies for producing and connecting regional deposition, systemic PK, and local lung tissue PK predictions, and (4) Model verification and validation for resulting predictions.

Ross Walenga
ORS | OGD | CDER

9:10 – 9:30

Session 3, Topic 1: Q&A Panel

Elizabeth Bielski, Liangfeng Han, Ross Walenga, Denise Conti, and Liang Zhao
(ORS | OGD)

Session 3, Topic 2: Topical Dermatologic Products

9:30 – 9:50

When Do Formulation Differences in Topical Dosage Forms Impact Their Function: Emerging Insights and Implications for Bioequivalence Approaches

This presentation will discuss recent results from GDUFA-funded research into the influence of differences in the composition of topical products on the resulting dermal pharmacokinetics and bioavailability. The potential implications of these results for bioequivalence approaches (based on topical formulation “similarity” or “no difference”) will be explored.

Sam Raney
ORS | OGD | CDER

9:50 – 10:10

In Vivo Dermal Microperfusion & Microdialysis Bioequivalence Approaches

This presentation will discuss recent pre-clinical and clinical study results from GDUFA-funded research including studies in human subjects comparing the cutaneous pharmacokinetics of different drugs from test and reference products. Specific considerations for the design of studies using emerging technologies like dermal microdialysis or microperfusion will be discussed.

Tannaz Ramezanli
ORS | OGD | CDER

10:10 – 10:30

Non-Invasive Raman Spectroscopy-Based Bioequivalence Approaches

This presentation will discuss recent results from GDUFA-funded research into emerging technologies like the use of Raman spectroscopy to non-invasively monitor the rate and extent to which drugs become available in the skin from topical dermatological products. The applications, limitations, and future implications of such emerging technologies as bioequivalence approaches will be contemplated.

Priyanka Ghosh
ORS | OGD | CDER

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DAY TWO: Wednesday, September 30, 2020

10:30 – 10:50

Session 3, Topic 2: Q&A Panel

Sam Raney, Tannaz Ramezanli, and Priyanka Ghosh

10:50 - 11:05: BREAK

Session 3, Topic 3: Emerging Use of Modeling and Simulation for Bioequivalence

11:05 – 11:25

Physiologically-based Pharmacokinetic Modeling to Guide Study Design and Product Development for Generic Dermatological Products

This presentation will illustrate how modeling and simulation approaches such as physiologically-based pharmacokinetic (PBPK) modeling can be used to advance drug product development and support alternative bioequivalence approaches for generic dermatological drug products. Model-informed dose selection for dermal-open flow microperfusion studies assessing the cutaneous pharmacokinetics of test and reference products and justifying acceptable differences in physical and structural composition between test and reference products by utilizing in silico in vitro permeation testing methodologies will be highlighted.

Eleftheria Tsakalozou
ORS | OGD | CDER

11:25 – 11:45

Model-Informed and Model-Integrated Approach in BE Assessment of Long-Acting Injectable Products

This presentation will explain challenges with BE studies for long-acting injectable (LAI) products and describe application of model-informed and model-integrated approach in BE study design and BE assessment of LAI products. Modeling and simulation provide an excellent opportunity to justify innovative BE study designs that can be used to shorten the BE study or improve study efficiency.

Satish Sharan
ORS | OGD | CDER

11:45 – 12:05

Session 3, Topic 3: Q&A Panel

Eleftheria Tsakalozou, Satish Sharan, and Lanyan (Lucy) Fang (ORS | OGD)

12:05 – 1:05 PM: LUNCH BREAK

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DAY TWO: Wednesday, September 30, 2020

Session 4: Practical Considerations in the Study Design and Data Evaluation Recommended in PSGs

Session Leads: **Andrew Babiskin** (ORS | OGD), **Ping Ren** (ORS | OGD), **and Pahala Simamora** (OLDP | OPQ)

Session 4, Topic 1: Oral Products

1:05 – 1:25

Biopharmaceutics Classification System Class 3 Waiver

This presentation will discuss Biopharmaceutics Classification System (BCS) Class 3-based biowaivers for generic drug development and approval. The talk will discuss the assessment criteria for BCS 3 waiver, including high solubility, Q1 the same/Q2 very similar formulation, and very rapid dissolution.

Yi Zhang
ORS | OGD | CDER

1:25 – 1:45

Using Physiologically-based Pharmacokinetic Absorption Modeling to Support Biopharmaceutics Classification System Class 3 Drug Waiver

This presentation will discuss the use of physiologically-based pharmacokinetic (PBPK) absorption modeling to support waivers for non-Q1/Q2 BCS class 3 generic drug products.

Fang Wu
ORS | OGD | CDER

1:45 – 2:05

Alternatives to f2 Testing for Dissolution Similarity – f2 Bootstrapping and MSD Method

This presentation will provide a comprehensive review on similarity factor (f2), f2 bootstrapping and multivariate statistical distance (MSD) methods for dissolution similarity assessment, including mathematical definition and assumption, conditions of use and interpretation of results. Some case examples will be discussed in this presentation.

Xiajing Gong
ORS | OGD | CDER

2:05 – 2:25

Session 4, Topic 1: Q&A Panel

Yi Zhang, Fang Wu, Xiajing Gong, and Liang Zhao (ORS | OGD)

2:25 - 2:40: BREAK

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DAY TWO: Wednesday, September 30, 2020

Session 4, Topic 2: In Vitro Feeding Tube Testing and GI Locally-Acting Products

2:40 – 3:00

A Closer Look into the Nasogastric and Gastric Feeding Tube Study Recommendations

This presentation will discuss the in vitro testing recommendations for comparative evaluation of Nasogastric (NG)/Gastrostomy (G) tubes on the performance of the proposed test product compared to the reference product. The presentation will specifically focus on the testing recommendations in the Lansoprazole Delayed Release, Orally Disintegrating Tablet draft guidance.

Katherine Tyner
Immediate Office | OPQ | CDER

3:00 – 3:20

In Vitro Enteral (Nasogastric and Gastric) Feeding Tube Testing of Generic Drug Products: Case Studies

This presentation will discuss case studies and focus on the challenges and practical considerations for testing and establishing equivalence of the test product with the reference product.

Mamta Kapoor
OLDP | OPQ | CDER

3:20 – 3:40

Practical Considerations for Bioequivalence of GI Locally-Acting Products

This presentation will provide an overview of the different classes of gastrointestinal (GI) locally-acting products. Given the diversity of bioequivalence recommendations, details will be provided on how the mechanism of action of the drug product informs the product-specific guidance.

Minglei Cui
OB | OGD | CDER

3:40 – 4:00

Session 4, Topic 2: Q&A Panel

Katherine Tyner, Mamta Kapoor, and Minglei Cui

4:00 – 4:10

Closing Remarks

Lei Zhang, PhD
Deputy Director
Office of Research and Standards
OGD | CDER | FDA

4:10 PM: EVENT ADJOURN

View the Speakers' Biographies

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