CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

2019 COMPLEX GENERIC DRUG PRODUCT DEVELOPMENT WORKSHOP - SEPTEMBER 25-26

COLLEGE PARK, MARYLAND
ATTEND IN PERSON OR VIA WEBCAST

Version 3, September 4, 2019
(use link below to check for updates)

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

Add to Your Calendar

FDA Acronyms & Abbreviations - CDER Guidance Documents

AGENDA

(Jump to Day Two)

Day One: Wednesday, September 25, 2019

7:15 a.m. Registration Opens

7:55 - 8:05: Administrative Announcements — **Jeff Kelly**

8:05 - 8:15

Welcome

Brenda Stodart
Captain, United States Public Health Service
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

8:15 - 8:30

Opening Remarks / Keynote

Norman E. "Ned" Sharpless
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration

Speakers' Biographies

Day One: Wednesday, September 25, 2019

SESSION 1: Overview and Update

8:30 – 9:00

Pre-ANDA Program Update

Karen Bengtson
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER

Suneela Prodduturi
Office of Pharmaceutical Quality (OPQ) | CDER

9:00 – 9:30

FDA's Inactive Ingredient Database: Improvements on the Path to 2020

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

9:30 – 10:00

Q&A and Panel Discussion

Karen Bengtson, Suneela Prodduturi, Susan Zuk, Kris André (ORS | OGD), **Robert Lionberger** (ORS | OGD)**, Jonathan Hughes** (Office of Generic Drug Products (OGDP) | OGD)

10:00 - 10:20: BREAK

SESSION 2: Scientific and Regulatory Advances for Generic Topical and Transdermal Product Development

10:20 – 10:40

Research Activities, Scientific Advances, & Modernization of Bioequivalence Standards for Generic Topical and Transdermal Products

Sam Raney
ORS | OGD | CDER

10:40 – 11:00

Innovation and Harmonization of Bioequivalence Standards for Generic Topical and Transdermal Products

Priyanka Ghosh
ORS | OGD | CDER

11:00 – 11:20

Best Practices & Efficient Strategies for Generic Topical Product Development

Tannaz Ramezanli
ORS | OGD | CDER

Day One: Wednesday, September 25, 2019

11:20 – 11:40

Critical Quality Considerations for Transdermal Delivery Systems

Brock Roughton
Office of Lifecycle Drug Products (OLDP) | OPQ | CDER

11:40 – 12:20

Q&A and Panel Discussion

Sam Raney, Priyanka Ghosh, Tannaz Ramezanli, Brock Roughton

12:20 - 1:30 p.m. LUNCH & NETWORKING - On your own. Click HERE for onsite dining options

SESSION 3: Characterization of Complex Injectable API and Formulations

1:30 – 1:50

Characterization and Comparative Evaluation Strategies to Demonstrate Complex API Sameness

Deyi Zhang
ORS | OGD | CDER

1:50 – 2:10

Complex Peptide ANDAs: Test and Reference Product Comparability Studies from a Quality Perspective

Cameron Smith
OLDP | OPQ | CDER

2:10 - 2:30

Development, Characterization, and Evaluation Considerations of Particle Analysis to Support Generic Product Quality and BE Determination

Xiaoming Xu
Office of Testing and Research (OTR) | OPQ | CDER

2:30 - 3:10

Q&A and Panel Discussion

Deyi Zhang, Cameron Smith, Xiaoming Xu, Ram Randad (ONDP | OPQ), **Darby Kozak** (ORS |OGD)

3:10 - 3:30: BREAK

Day One: Wednesday, September 25, 2019

SESSION 4: Bioequivalence Approaches for Complex Injectable API and Formulations

3:30 – 3:50

Bioequivalence Approaches for Long Acting Drug Products: Regulatory and Scientific Considerations

Yan Wang
ORS | OGD | CDER

3:50 – 4:10

Characterization and Comparative Evaluation Strategies to Demonstrate Complex Excipient Sameness

Bin Qin
ORS | OGD | CDER

4:10 – 4:30

Considerations on In Vitro Drug Release Testing for Long Acting Drug Products for Quality Control Purpose

Vidula Kolhatkar
Office of New Drug Products (ONDP) | OPQ | CDER

4:30 – 5:10

Q&A and Panel Discussion

Yan Wang, Bin Qin, Vidula Kolhatkar, Bing Cai (OLDP | OPQ)

5:10 p.m. - DAY ONE ADJOURN

5:30 - 7:00 PM: NETWORKING OPPORTUNITY

Onsite attendees are invited to gather at THE HOTEL's Lobby Bar to continue the conversation with fellow attendees.

Speakers' Biographies

Day Two: Thursday, September 26, 2019

7:30 a.m. Registration Opens

7:55 - 8:05: Administrative Announcements — **Jeff Kelly**

8:05 - 8:10

Welcome

Forest "Ray" Ford, Jr.
DDI | OCOMM | CDER

SESSION 5: Drug-Device Combination Products - Injectable Products

8:10 – 8:30

Overview of Drug-Device Combination and What Constitutes Complex Drug-Device Combination

Lisa Bercu
OGDP | OGD | CDER

8:30 – 8:50

Overview of General Guidance on Comparative Analyses From a Clinical Perspective

Michelle Lin
Office of Bioequivalence (OB) | OGD | CDER

8:50 – 9:10

Evaluation of Generic Complex Drug-Device Products: Injectable Product Considerations from a Quality Perspective

Bita Mirzai Azarm
OLDP | OPQ | CDER

9:10 – 9:30

Evaluation of Generic Complex Drug-Device Products: Injectable Product Considerations from a Clinical Perspective

Andrew Fine
OB | OGD | CDER

9:30 – 10:10

Q&A and Panel Discussion

Lisa Bercu, Bing Cai, Kimberly Witzmann (OB | OGD), **Steven Hertz** (Office of Process and Facilities (OPF) | OPQ)**, Alan Stevens** (Center for Devices and Radiological Health (CDRH)

10:10 - 10:30: BREAK

Day Two: Thursday, September 26, 2019

SESSION 6: Complex Drug-Device Combination Products - Orally-Inhaled and Nasal Drug Products (OINDPs)

10:30 – 10:45

Product-Specific Guidance (PSG) Recommendations and Updates for OINDPs

Bryan Newman
ORS | OGD | CDER

10:45 – 11:00

Considerations for OINDP Pre-ANDA Meeting Requests

Denise Conti
ORS | OGD | CDER

11:00 – 11:20

Comparative Analyses: Device and User Interface Considerations

Kimberly Witzmann
ORS | OGD | CDER

11:20 – 11:40

Bioequivalence Considerations for Conducting Bridging Studies with OINDPs

Tian Ma
OB | OGD | CDER

11:40 – 12:00

CMC Updates and Other Considerations for OINDPs

Fang Yuan
OLDP | OPQ | CDER

12:00 – 12:30

Q&A and Panel Discussion

Bryan Newman, Denise Conti, Kimberly Witzmann, Tian Ma, Fang Yuan, Bhagwant Rege (OLDP | OPQ)

12:30 - 1:40 p.m. LUNCH & NETWORKING - On your own. Click HERE for onsite dining options

Speakers' Biographies

Day Two: Thursday, September 26, 2019

SESSION 7: Quantitative Methods and Modeling-Informed Regulatory Decision Making

1:40 – 1:50

General Overview: The Use of Quantitative Methods and Modeling to Facilitate Generic Drug Development and Regulatory Assessment

Liang Zhao
ORS | OGD | CDER

1:50 – 2:10

PK/PD Meta-analysis of Abuse Deterrent Opioid Drug Products: PSG Development, Research and ANDA Assessment

Lanyan (Lucy) Fang
ORS | OGD | CDER

2:10 – 2:30

Regulatory Considerations on Dose-scale Analysis in Assessing Pharmacodynamic Equivalence

Xiajing Gong
ORS | OGD | CDER

2:30 – 2:50

Physiologically-based Pharmacokinetic Modeling and Simulation Approaches: Best Practices for Regulatory Applications Related to Locally-acting Generic Drugs

Eleftheria Tsakalozou
ORS | OGD | CDER

2:50 – 3:10

Credibility Establishment for Computational Fluid Dynamics Models of Complex Generic Drug Delivery

Ross Walenga
ORS | OGD | CDER

3:10 – 3:25: BREAK

3:25 – 3:45

Application of Quantitative Clinical Pharmacology (QCP) in Development of Long Acting Injectable Products

Satish Sharan
ORS | OGD | CDER

Day Two: Thursday, September 26, 2019

3:45 – 4:25

Q&A and Panel Discussion

Liang Zhao, Yaning Wang (OCP | OTS), **Robert Lionberger** (ORS | OGD), **Murray Ducharme** (Learn and Confirm, Inc.)

4:25 – 4:30

Closing Remarks

Robert Lionberger, PhD
Director, Office of Research and Standards
OGD | CDER

4:30 PM: ADJOURN

Speakers' Biographies

For updates and additional information, please visit SBIAevents.com