DIA

Complex Drug-Device Generic Combination Products Meeting

October 9-10 | Sheraton Silver Spring Hotel | Silver Spring, MD

PROGRAM CHAIR

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Division Director, Division of Therapeutic Performance, Office of Generic Drugs
CDER, FDA

PROGRAM COMMITTEE

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Regulatory Counsel, Office of Generic Drug Policy, Office of Generic Drugs
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CDER, FDA

Overview

Complex Generic Drugs are a large and diverse group of products with complex active ingredients or sites of action and complex drug-device combination products. They provide important therapies to patients, for example, metered dose inhalers for treating asthma and drugs administered by auto-injectors and prefilled syringes. Because this diverse collection of drug products has one or more elements that are more complex than a simple dosage form, new complexities in the methodologies used for establishing bioequivalence are introduced, thus impeding patient access to the more affordable generic versions of these life-saving medicines.

To receive email updates from FDA's Generic Drugs Program, please visit http://go.fda.gov/subscriptionmanagement, enter your email address, and choose "Generic Drugs Updates".

Highlights

- Hear from FDA staff from CDER, Office of Generic Drugs, Office of Pharmaceutical Quality, CDRH, Office of Combination Products, and other industry experts
- Gain a better understanding of the current regulatory landscape for generic combination drug-device products
- Examine scientific concerns and recent research advances associated with the development of generic drug-device combination products
- Co-located conference the day after the meeting: Combination Products Conference, October 11-12

Target Audience

Professionals involved in:

- Biopharmaceutical, Device, and Combination Product R&D and Development
- Generics Development
- Clinical Research
- Pharmacology
- Regulatory Affairs
- Safety/Pharmacovigilance
- Quality Assurance and Control
- CMC/GMP
- Policy
- Consulting, Legal, Government Affairs
- Business Development

Schedule At-A-Glance

DAY ONE | TUESDAY, OCTOBER 9		ROOM
7:30AM-5:30PM	Registration	Cypress Foyer
7:30-8:15AM	Continental Breakfast and Networking	Hawthorn
8:15-8:25AM	**DIA Welcome and Opening Remarks**	Cypress Ballroom
8:25-8:35AM	**Welcome and Opening Remarks**	Cypress Ballroom
8:35-9:05AM	**Keynote Address**	Cypress Ballroom
9:05-10:05AM	**Session 1:** Generic Drug-Device Combination Products: Understanding the Regulatory Expectations for Drug-Device Combination Products Submitted in an ANDA	Cypress Ballroom
10:05-10:30AM	Refreshment and Networking Break	Hawthorn
10:30AM-12:30PM	**Session 1:** Generic Drug-Device Combination Products: Understanding the Regulatory Expectations for Drug-Device Combination Products Submitted in an ANDA (Continued)	Cypress Ballroom
12:30-1:30PM	Luncheon and Networking	Magnolia Ballroom
1:30-3:30PM	**Session 2:** Bioequivalence Considerations for Complex Generic Inhalation, Nasal, and Auto-Injector Drug Device Combination Products	Cypress Ballroom
3:30-4:00PM	Refreshment and Networking Break	Hawthorn
4:00-6:00PM	**Session 2:** Bioequivalence Considerations for Complex Generic Inhalation, Nasal, and Auto-Injector Drug Device Combination Products (Continued)	Cypress Ballroom
6:00-7:00PM	Networking Reception	Magnolia Ballroom

DAY TWO | WEDNESDAY, OCTOBER 10		ROOM
7:30AM-5:00PM	Registration	Cypress Foyer
7:15-8:15AM	Continental Breakfast and Networking	Hawthorn
8:15-8:30AM	**Welcome to Day Two**	Cypress Ballroom
8:30-10:00AM	**Session 3:** Quality Considerations for Generic Drug-Device Combination Products	Cypress Ballroom
10:00-10:30AM	Refreshment and Networking Break	Hawthorn
10:30AM-12:30PM	**Session 3:** Quality Considerations for Generic Drug-Device Combination Products (Continued)	Cypress Ballroom
12:30-1:30PM	Luncheon and Networking	Magnolia Ballroom
1:30-2:30PM	**Session 4 Part A:** Ongoing Research in Long-Acting Generic Drug-Device Implant	Cypress Ballroom
2:30-3:00PM	Refreshment and Networking Break	Hawthorn
3:00-4:30PM	**Session 4 Part B:** Scientific Research, Development, and Regulatory	Cypress Ballroom
4:30-5:00PM	Panel Discussion	Cypress Ballroom
5:00-5:15PM	**Closing Remarks**	Cypress Ballroom

Learning Objectives

At the conclusion of this meeting, participants should be able to:

- Explore the statutory framework and associated regulatory and policy considerations for drug-device combination products submitted in an ANDA
- Identify and address scientific considerations for establishing bioequivalence for different complex drug-device combination delivery methods
- Identify specific product quality challenges in developing different approaches to drug-device combination product manufacturing to meet sameness in product performance and cGMP requirements
- Discuss ideas for improving communication and collaboration between industry, academia, and the agency in developing novel methods and standards for assessing the sameness of complex generic drug-device combination products

Continuing Education Credits

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ACPE CREDIT REQUESTS MUST BE SUBMITTED BY NOVEMBER 23, 2018

Type of Activity: Knowledge

Participants are able to receive an ACPE statement of credit for daily attendance. No partial daily credit will be awarded.

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Continuing Education Credit Allocation

Meeting Day One: Pharmacy 7.5 Contact Hours or .75 CEUs, UAN: 0286-0000-18-071-L04-P

Meeting Day Two: Pharmacy 6.75 Contact Hours or .675 CEUs, UAN: 0286-0000-18-072-L04-P

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DAY ONE | TUESDAY, OCTOBER 9

7:30AM-5:30PM — **Registration**

7:30-8:15AM — **Continental Breakfast and Networking**

8:15-8:25AM — **DIA Welcome and Opening Remarks**

Session Chair
Sudip Parikh, PhD, Senior Vice President and Managing Director, DIA Americas, DIA

8:25-8:35AM — **Welcome and Opening Remarks**

Session Chair
Markham C. Luke, MD, PhD, Division Director, Division of Therapeutic Performance, Office of Generic Drugs, CDER, FDA

8:35-9:05AM — **Keynote Address**

Keynote Speaker
Anna K. Abram, Deputy Commissioner for Policy, Planning, Legislation and Analysis, Office of The Commissioner, FDA

9:05-10:05AM — **Session 1:** Generic Drug-Device Combination Products: Understanding the Regulatory Expectations for Drug-Device Combination Products Submitted in an ANDA

Session Chair
Andrew A. LeBoeuf, MS, JD, Regulatory Counsel, Office of Generic Drug Policy, Office of Generic Drugs CDER, FDA

The session will provide a broad overview of the regulatory expectations for drug-device combination products submitted under an abbreviated new drug application (ANDA). Presenters will provide insight on the regulatory definition for combination products, outline the key regulatory considerations in seeking approval of a generic combination product, describe efforts underway to enhance inter-center communication and coordination of submissions, and an explanation of the associated cGMP and safety reporting requirements. Information on how ANDA applicants may interact with FDA during product development will also be included. The session will conclude with a panel discussion, intended to engage participants in the audience and on the panel.

Combination Products 101
John Barlow Weiner, JD, Associate Director for Policy, Office of Combination Products, OSMP, FDA

Overview of Regulatory and User-Interface Considerations, and the Role of Comparative Analyses, in Developing a Generic Drug-Device Combination Product in an ANDA
Andrew Leboeuf, MS, JD, Regulatory Counsel, Office of Generic Drug Policy, Office of Generic Drugs, CDER, FDA

Introduction to CGMPs for Combination Products
Melissa Burns, MS, Senior Program Manager, Office of Combination Products, OSMP, FDA

The GDUFA II Pre-ANDA Program
Kris Andre, MS, Associate Director for Regulatory Affairs, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Panel Discussion
Moderator:
Martha Nguyen, JD, Director, Division of Policy Development, Office of Generic Drug Policy, Office of Generic Drugs, CDER, FDA

Panelists:
Andrew LeBoeuf, MS, JD, Regulatory Counsel, Office of Generic Drug Policy, Office of Generic Drugs, CDER, FDA

Kris Andre, MS, Associate Director for Regulatory Affairs, Office of Research and Standards, Office of Generic

Drugs, CDER, FDA

John Barlow Weiner, JD, Associate Director for Policy, Office of Combination Products, OSMP, FDA

Melissa Burns, MS, Senior Program Manager, Office of Combination Products, OSMP, FDA

Alan Stevens, ME in Reliability Engineering, Branch Chief, General Hospital Devices Branch, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices, Office of Device Evaluation, CDRH, FDA

Brian McCormick, Vice President and Chief Regulatory Counsel, Teva Pharmaceuticals

10:05-10:30AM — **Refreshment and Networking Break**

10:30AM-12:30PM — **Session 1:** Generic Drug-Device Combination Products: Understanding the Regulatory Expectations for Drug-Device Combination Products Submitted in an ANDA (Continued)

12:30-1:30PM — **Luncheon and Networking**

1:30-3:30PM — **Session 2:** Bioequivalence Considerations for Complex Generic Inhalation, Nasal, and Auto Injector Drug-Device Combination Products

Session Chair
Kimberly Witzmann, MD, Medical Officer, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

This session will present an overview of complex orally inhaled and nasal drug products (OINDPs) as well as complex auto-injector drug-device combination products. We will discuss the current recommendations for establishing bioequivalence as described in product-specific guidances (PSGs), the remaining scientific questions and challenges, and how new tools and innovations can help to inform product development and support the regulatory assessment process, with the goal of increasing access to safe, affordable generic drugs for the American public.

Overview of Complex Generic Inhalation and Auto-Injector Drug-Device Combination Products
Denise Conti, PhD, Reviewer, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Pharmacokinetic Comparison of Locally-Acting Dry Powder Inhalers
Guenther Hochhaus, PhD, Professor, University of Florida

Jürgen Bullita, PhD, Associate Professor, College of Pharmacy, University of Florida

Enhanced Analytical Tools for Bioequivalence Evaluation of Nasal Spray Drug Products
Jason Rodriguez, PhD, Laboratory Chief, Branch 1, Division of Pharmaceutical Analysis, Office of Testing and Research, Office of Pharmaceutical Quality, CDER, FDA

Clinical Considerations for the Design and Conduct of Comparative Clinical Endpoint Studies for Establishing Bioequivalence of Inhalation and Nasal Drug Products
Carol Kim, PharmD, Acting Team Lead, Division of Clinical Review, Office of Bioequivalence, Office of Generic Drugs, CDER, FDA

Impact of Orally Inhaled Drug Product Design Complexity on Quality and Performance
Anthony J. Hickey, PhD, Distinguished Fellow, Research Triangle Park

User Interface Considerations on Bioequivalence and Therapeutic Equivalence for Complex Generic Orally-Inhaled, Nasal, and Auto-Injector Drug Products
Kimberly Witzmann, MD, Medical Officer, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

3:30-4:00PM — **Refreshment and Networking Break**

4:00-6:00PM

Session 2: Bioequivalence Considerations for Complex Generic Inhalation, Nasal, and Auto Injector Drug-Device Combination Products (Continued)

Session Chair
Kimberly Witzmann, MD, Medical Officer, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Panel Discussion
Moderator:
Roisin Wallace, Vice President, Head of Global Device Development, Mylan, Ireland

Panelists:
Denise Conti, PhD, Reviewer, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Guenther Hochhaus, PhD, Professor, University of Florida

Jason Rodriguez, PhD, Laboratory Chief, Branch 1, Division of Pharmaceutical Analysis, Office of Testing and Research, Office of Pharmaceutical Quality, CDER, FDA

Sarah Yim, MD, Director, Division of Clinical Review, Office of Bioequivalence, Office of Generic Drugs, CDER, FDA

Anthony J. Hickey, PhD, Distinguished Fellow, Research Triangle Park

Kimberly Witzmann, MD, Medical Officer, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

6:00-7:00PM

Networking Reception

DAY TWO | WEDNESDAY, OCTOBER 10

7:30AM-5:00PM

Registration

7:15-8:15AM

Continental Breakfast and Networking

8:15-8:30AM

Welcome to Day Two

Session Chair
Markham C. Luke, MD, PhD, Division Director, Division of Therapeutic Performance, Office of Generic Drugs, CDER, FDA

8:30-10:00AM

Session 3: Quality Considerations for Generic Drug-Device Combination Products

Session Chair
Susan Rosencrance, PhD, Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

This session will focus on quality considerations for generic drug-device combination products. In addition, the presentations in this session will provide scientific discussion on quality issues related to various drug-device combination products as well as manufacturing related issues.

Product Quality Considerations for Transdermal Delivery Systems (TDS) and Metered Dose Inhalers (MDIs)
Brock Roughton, PhD, Acting Quality Assessment Lead, Division of Modified Release Products, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Intira Coowanitwong, PhD, Acting Quality Assessment Lead, Division of Modified Release Products, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Quality Expectations for Injectable and Other Liquid-Based Generic Combination Products
Bing Cai, PhD, Director, Division of Liquid-Based Products, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Transdermal Systems: Considerations for the Manufacturing Process Assessment
James Norman, PhD, Senior Chemist, Division of Process Assessment II, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

Facility Inspection Considerations for Generic Drug-Device Combination Products
Steven Hertz, MS, MBA, PE, Consumer Safety Officer, Division of Inspectional Assessment I, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

Device Design and Quality Evaluation for Generic Combination Products
Alan Stevens, ME in Reliability Engineering, Branch Chief, The General Hospital Devices Branch, Division of Anesthesiology, Gen Hospital, infection control, and Dental devices, Office of Device Evaluation, CDRH, FDA

10:00-10:30AM — **Refreshment and Networking Break**

10:30AM-12:30PM — **Session 3:** Quality Considerations for Generic Drug-Device Combination Products (Continued)

Session Chair
Susan Rosencrance, PhD, Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Panel Discussion
Panelists:
Bing Cai, PhD, Director, Division of Liquid-Based Products, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Brock Roughton, PhD, Acting Quality Assessment Lead, Division of Modified Release Products, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Intira Coowanitwong, PhD, Acting Quality Assessment Lead, Division of Modified Release Products, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

James Norman, Senior Chemist, Division of Process Assessment II, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

Steven Hertz, MS, MBA, PE, Consumer Safety Officer, Division of Inspectional Assessment I, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

Alan Stevens, ME in Reliability Engineering, Branch Chief, The General Hospital Devices Branch, Division of Anesthesiology, Gen Hospital, infection control, and Dental devices, Office of Device Evaluation, CDRH, FDA

Gary Henniger, Sr Director, Global Device R&D Operations, Teva Pharmaceuticals

12:30-1:30PM — **Luncheon and Networking**

1:30-2:30PM — **Session 4 Part A:** Ongoing Research in Long-Acting Generic Drug-Device Implant Products

Session Chair
Darby Kozak, PhD, Lead for Complex Drug Substances and Dosage Forms, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

This session will highlight the latest scientific research on physicochemical and bioequivalence testing for IUD products.

Research Related to Design and Composition Considerations in the Development of Generic Intrauterine Devices
Yan Wang, PhD, Scientific Lead for Long Acting Injectable and Implant Device Products, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Application of Modeling and Simulation in Establishing Appropriate Bioequivalence Limits for Long Acting Intrauterine Product
Satish Sharan, PhD, Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

An Accelerated In Vitro Release Testing Method to Assess Q1/Q2 Formulated Levonorgestrel Intrauterine Devices
Diane Burgess, PhD, Board of Trustees Distinguished Professor of Pharmaceutics, University of Connecticut, Department of Pharmaceutical Sciences

2:30-3:00PM — **Refreshment and Networking Break**

3:00-4:30PM — **Session 4 Part B:** Scientific Research, Development, and Regulatory Considerations for Complex Generic Transdermal Products

Session Chair
Sam G. Raney, MS, PhD, Lead for Topical and Transdermal Drug Products, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

This session will include an introductory presentation that discusses some of the unique and complex issues related to TDS products, as well as presentations from speakers offering academic, industry, and regulatory perspectives on the scientific research, product development, and regulatory perspectives. The session will conclude with a 30-minute panel discussion, intended to engage all the participants in the audience and on the panel.

Facilitating Patient Access to High-Quality Generic Transdermal Products: The Role of FDA and GDUFA
Sam G. Raney, MS, PhD, Lead for Topical and Transdermal Drug Products, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Scientific Challenges for Generic Transdermal Products: Recent Advances and Future Research
Audra Stinchcomb, PhD, Professor of Pharmaceutical Sciences, University of Maryland School of Pharmacy

Product Development Challenges for Generic Transdermal Products: An Industry Perspective
Charles DiLiberti, MS, President, Montclair Bioequivalence Services, LLC

Combination Drug-Device Products as Complex Generic Drugs – Summary of Presentations and Horizon Scanning for Future Scientific Research
Markham C. Luke, MD, PhD, Division Director, Division of Therapeutic Performance, Office of Generic Drugs, CDER, FDA

4:30-5:00PM — **Panel Discussion**

Moderator
Markham C. Luke, MD, PhD, Division Director, Division of Therapeutic Performance, Office of Generic Drugs, CDER, FDA

Panelists
Darby Kozak, PhD, Lead for Complex Drug Substances and Dosage Forms, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Jeff Jiang, PhD, Deputy Director, Division of Therapeutic Performance, Office of Generic Drugs CDER, FDA

Sam G. Raney, MS, PhD, Lead for Topical and Transdermal Drug Products, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Andrew LeBoeuf, MS, JD, Regulatory Counsel, Office of Generic Drug Policy, Office of Generic Drugs, CDER, FDA

Charles DiLiberti, MS, President, Montclair Bioequivalence Services, LLC

5:00-5:15PM — **Closing Remarks**

Combination Drug Products and Generic Drug Science
Robert Lionberger, PhD, Director for The Office of Research and Standards, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

5:15PM — **Meeting Adjourned**