Small Business and Industry Assistance
Generic Drugs Forum 2025

April 9 & 10

Version 6 – Updated March 7, 2025

For files and resources, please visit
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AGENDA

All times are Eastern (EST UTC-4)

View Start Time on World Clock

DAY ONE: Wednesday, April 9, 2025

8:30 – 8:45

Welcome & Administrative Overview

Brenda Stodart, PharmD, MS, BCGP, RAC
Captain, United States Public Health Service (USHPS)
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 – 8:55

Office of Generic Drugs (OGD) Keynote

Darby Kozak, PhD
Deputy Director
Office of Generic Drugs (OGD)
CDER

8:55 – 9:05

Office of Pharmaceutical Quality (OPQ) Keynote

Geoffrey Wu, PhD
Commander | USPHS
Acting Director
Office of Product Quality Assessment I (OPQA I)
Office of Pharmaceutical Quality (OPQ) | CDER

DAY ONE: Wednesday, April 9, 2025

9:05 – 9:25

Abbreviated New Drug Applications (ANDA) Missed Goal Dates: An Update on Metrics and Internal Communications

This session will provide information on the number and types of missed application goal dates, and the Agency's internal efforts to complete the assessment.

Edward (Ted) Sherwood
Director
Office of Regulatory Operations (ORO)
OGD | CDER

9:25 – 9:45

Transparency Pilot for Enhanced Communications

This session will provide an overview of the Office of Generic Drug's enhanced communication pilot with generic drug applicants to increase transparency related to potential or missed goal date Abbreviated New Drug Applications (ANDAs).

Scott Vehovic
Commander | USPHS
Supervisory Project Manager
Division of Project Management (DPM)
ORO | OGD | CDER

9:45 – 10:05

Request For Reconsideration: Process Overview and Best Practices for FDA Evaluation

This session will provide a brief overview of the Request for Reconsideration (RFR) process at the Division level under Generic User Fee Amendment (GDUFA) with a focus on how to submit an RFR for FDA evaluation.

Joe Shin, PharmD
Lead Regulatory Health Project Manager
DPM | ORO | OGD | CDER

10:05 – 10:25

Request for Reconsideration Under Generic Drug User Fee Amendment (GDUFA) III – Overview and Experience from Bioequivalence Perspectives

This session will provide an overview on the assessment of Request for Reconsideration (RFR) in ANDA submission from bioequivalence perspectives based on experiences and expectations under GDUFA III.

Yi Zhang, PhD
Associate Director
Division of Bioequivalence III (DBIII)
Office of Bioequivalence (OB) | OGD | CDER

10:25 – 10:45

Questions & Panel Discussion

Ted Sherwood, Scott Vehovic, Joe Shin and **Yi Zhang**

10:45 – 11:05: BREAK

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DAY ONE: Wednesday, April 9, 2025

11:05 – 11:25

Best Practices for Generic Drug Labeling

This session will provide an overview of ANDA labeling-related topics to help applicants provide high-quality labeling submissions and potentially reduce review cycles.

Churg (Stella) Chan, PharmD, BCPS
Pharmacist | Division of Labeling Review (DLR)
ORO | OGD | CDER

11:25 – 11:45

Project Managing Drug Assessors Under GDUFA III Regulations

This presentation will cover the GDUFA III and its significant changes from GDUFA II. It will highlight the roles of Regulatory Business Process Managers (RBPMs) in managing applications and the scientific assessors responsible for reviewing them. Additionally, the audience will gain insights into the tools used by RBPMs to efficiently lead teams and projects, ensure goal dates are met, and manage communication with external firms.

Nuri Tawwab, PharmD, MPH
Lieutenant Commander | USPHS
Stakeholder Engagement Team
Division of Prevention Communication and Public Engagement (DPCPE)
Center for Substance Abuse Prevention (CSAP)
Substance Abuse and Mental Health Services Administration (SAMSHA)

11:45 – 12:05

Minor Regulatory Errors with Major Consequences

This presentation will provide Industry with the required documents needed moving toward approval.

Thu (Suzanne) Phan, PharmD
Pharmacist
Division of Legal & Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP) | OGD | CDER

12:05 – 12:25

Questions & Panel Discussion

Churg (Stella) Chan, Nuri Tawwab, Thu (Suzanne) Phan
and
Heather Strandberg, PharmD
Pharmacist
DLRS | OGDP | OGD | CDER

12:25 – 1:25: LUNCH BREAK

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DAY ONE: Wednesday, April 9, 2025

1:25 – 1:45

Considerations when Submitting Proposed Excipient Levels in Inactive Ingredient Controlled Correspondences

This session will cover in detail the nuances considered for inactive ingredient Controlled Correspondence reviews.

Zakia R. Williams-Greene, PhD
Senior Pharmacologist
Division of Bioequivalence III (DBIII) | OB | OGD | CDER

1:45 – 2:05

Assessment of Inactive Ingredients in Generic Drug Applications: Building a Global Understanding

This session will provide the commonalities that exist between the Agency and other regulatory jurisdictions regarding inactive ingredient evaluation.

Pamela Dorsey, MS, PhD
Senior Pharmacologist
DBIII | OB | OGD | CDER

2:05 – 2:25

How to Leverage the Inactive Ingredient Database (IID) and Safety Justification

This session will provide an overview of the Inactive Ingredient Database (IID) and describe how to leverage the IID and Safety justification

Qing Liu, PhD
Deputy Director
DBI | OB | OGD | CDER
and
Julia Yang, PhD
Pharmacologist
Division of Pharmacology/Toxicology Review (DPTR)
Office of Safety & Clinical Evaluation (OSCE) | OGD | CDER

2:25 – 2:40

Questions & Panel Discussion

Zakia Williams-Greene, Pamela Dorsey, Julia Yang, and **Qing Liu**

2:40 – 3:00: BREAK

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DAY ONE: Wednesday, April 9, 2025

3:00 – 3:20

Product Specific Guidance (PSG) Program Overview

This presentation will provide an overview of the U.S FDA PSG program, including how and when PSGs are published, navigating the online available resources, and ways to communicate with FDA on published PSGs.

Joseph Kotysbar, PharmD
Regulatory Health Project Manager
Office of Research and Standards (ORS)
OGD | CDER

3:20 – 3:40

Pre-Abbreviated New Drug Application (ANDA) Meetings: Process and Best Practices

This presentation will provide an overview of the pre-ANDA scientific meeting process related to topics that provide prospective applicants information to assist in high-quality meeting request submissions.

Caliope Sarago, MHSA
Team Lead, Regulatory Health Project Manager
ORS | OGD | CDER

3:40 – 4:00

Experiences from Post-Complete Response Letter (CRL) Scientific Meetings in GDUFA III

This session will provide an overview of Post-CRL Scientific Meeting Requests (post-CRSMRs) per the GDUFA III Commitment Letter and learn when and how to utilize the post-CRSMRs to support generic drug development.

Arun Agrawal, PhD
Pharmacologist
DBI | OB | OGD | CDER

DAY ONE: Wednesday, April 9, 2025

4:00 – 4:20

Common Discrepancies Observed on the Form 356h with the Abbreviated New Drug Application (ANDA) Submission

This presentation will cover discrepancies commonly observed on the form 356h with the ANDA submission. Deviations on the form 356h may lead to an increased number of facility information requests, potentially delaying the approvability of the ANDA. Attendees will learn best practices for completing the form 356h and strategies to help them avoid these common pitfalls to ensure a more streamlined submission process, reduce the risk of deficiencies, and limit delays in the review timeline

Onyekachukwu (Onyeka) Ihezie, PharmD
Regulatory Business Process Manager
Division of Regulatory and Business Process Management I (DRBPMI)
OPRO | OPQ | CDER
and
Thaoly Nguyen, PharmD
Regulatory Business Process Manager
DRBPMIII | OPRO | OPQ | CDER

4:20 – 4:45

Questions, Panel Discussion & Closing

Joseph Kotysbar, Caliope Sarago, Arun Agrawal, Onyeka Ihezie and **Thaoly Nguyen**
and
Haitao Li, PhD
Supervisor
Division of Pharmaceutical Manufacturing Assessment V (DPMAV)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

4:45: ADJOURN DAY ONE

5:00 – 6:00 PM: NETWORKING OPPORTUNITY

Onsite attendees are invited to gather at The Corby Kitchen Bar to continue the conversation with fellow attendees.

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DAY TWO: Thursday, April 10, 2025

8:30 – 8:40

Administrative Overview

Kori Adair, PharmD
Pharmacist
Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

8:40 – 9:00

General Quality Considerations of Drug Products Labeled for Alternate Dosing Administration

This presentation will provide an overview of general quality considerations of Drug Product Labeled for Alternate Dosing Administration such as product administered by use of vehicles after crushing or sprinkling, via in-vitro feeding tube, etc. The presentation will cover relevant FDA Guidances along with quality information in generic drug applications.

Ravikanth Kona, PhD
Pharmaceutical Scientist
Division of Product Quality Assessment I (DPQA I)
Office of Product Quality Assessment I (OPQA I)
Office of Pharmaceutical Quality (OPQ) | CDER

9:00 – 9:20

Nitrosamine Related Guidance

This presentation will provide an overview of the current regulatory landscape surrounding nitrosamines and the latest guidelines and recommendations from a regulatory perspective regarding nitrosamine detection, risk assessment, and mitigation strategies. Attendees will gain insights into best practices for ensuring product safety and compliance with evolving nitrosamine-related regulations.

Reynolds (Rey) Cantave, PharmD
Senior Regulatory Health Project Manager
Enterprise Project Management Staff
Office of Quality Assurance (OQA) | OPQ | CDER

9:20 – 9:35

Bioequivalence Approaches for Nitrosamine Impacted Generic Drug Applications: Case Studies

This presentation will provide an overview of case studies related to bioequivalence approaches for nitrosamine-impacted generic drug applications.

Paramjeet Kaur, PhD
Team Leader
Division of Bioequivalence II (DB II)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD) | CDER

9:35 – 9:55

Questions & Panel Discussion

Ravikanth Kona, Reynolds (Rey) Cantave, Paramjeet Kaur,
and
Truong Quach, PharmD
Team Lead
Division of Orange Book Publication and Regulatory Assessment (DOBPRA)
Office of Generic Drug Policy (OGDP)
OGD | CDER

9:55 – 10:15: BREAK

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DAY TWO: Thursday, April 10, 2025

10:15 – 10:30

Impact of ICH M13A Implementation on Bioequivalence Assessment: Removal of Data Due to Low Exposure

This presentation will introduce the recent ICH M13A Guidance: Bioequivalence for Immediate-Release (IR) Solid Oral Dosage Forms (Oct 2024) exception for the removal of low exposure subjects in in vivo bioequivalence (BE) studies, which represents a change from the previous practice. Case studies will be presented to demonstrate how ICHM13A has been implemented in BE assessment with respect to low exposure data removal.

Diana Vivian, PhD
Associate Division Director
DBII | OB | OGD | CDER

10:30 – 10:50

ANDA Common Major Deficiencies

This presentation will provide an overview of major deficiencies trends from recent ANDA complete response letters by assessment discipline, ANDA assessment cycle, and ANDA applicant company size.

Darby Kozak, PhD
Deputy Director
OGD | CDER

10:50 – 11:05

Common Bioequivalence (BE) Deficiencies Identified in ANDAs Associated with Solid Oral Extended-Release Drug Products in Various Therapeutic Areas

This presentation will provide an overview of common BE deficiencies identified in ANDAs associated with solid oral extended-release (ER) drug products in various therapeutic areas.

Juhyun Kim, PhD
Senior Pharmacologist
DBIII | OB | OGD | CDER

11:05 – 11:25

Common Clinical Deficiencies in Abbreviated New Drug Applications (ANDAs) Containing Comparative Clinical Endpoint Studies

This presentation will provide an overview of comparative clinical endpoint BE study and Irritation/sensitization/adhesion studies. It will also discuss common clinical deficiencies identified in the review of these studies. The purpose is to assist applicants in submitting high-quality studies and potentially reduce the review cycle.

Ying Fan, PhD
Team Lead | Division of Clinical Review (DCR)
Office of Safety and Clinical Evaluation (OSCE)
OGD | CDER

11:25 – 11:50

Questions & Panel Discussion

Diana Vivian, Darby Kozak, Juhyun Kim and **Ying Fan**

11:50 - 12:50: LUNCH BREAK

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DAY TWO: Thursday, April 10, 2025

12:50 – 1:10

GDUFA III Impact on Drug Master File (DMF) Assessment

This presentation provides a brief discussion on the impact of GDUFA III Prior Assessment and solicited off-cycle processes on the DMF assessment, with an emphasis on current GDUFA III data and some best practices for industry.

Jayani Perera, PhD
Senior Chemist
Division of Product Quality Assessment XIX (DPQAXIX)
Office of Product Quality Assessment III (OPQAIII)
OPQ | CDER

1:10 – 1:30

Common Deficiencies in Drug Master Files (DMFs)

This presentation will provide a quick overview of common deficiencies found in DMF submissions from a regulatory perspective.

David Green, MS
Senior Pharmaceutical Quality Assessor
DPQAXVII | OPQAIII | OPQ | OGD | CDER

1:30 – 1:50

Common (OPQ) Deficiencies in Abbreviated New Drug Applications (ANDAs)

This presentation will provide an overview of major deficiency trends in first assessment cycle of ANDAs. The presenter will share common quality major deficiencies issued by assessment disciplines and highlight areas to improve ANDA submission quality.

Fang Yuan, PhD
Senior Pharmaceutical Scientist
Immediate Office (IO)
OPQAI | OPQ | CDER

1:50 – 2:10

Navigating Challenges in Drug Manufacturing: Common Process Deficiencies and Pre-Approval Inspection Observations

The presentation aims to provide an overview of common deficiencies observed in drug manufacturing process and the critical observations form pre-approval inspections that significantly impact generic drug applications. By examining the broad trends, the attendees will gain a dapper understanding of the key areas that require attention to ensure compliance and quality in drug manufacturing.

Andrew Idzior
Chemist
Office of Pharmaceutical Manufacturing Assessment (OPMA) | OPQ | CDER

DAY TWO: Thursday, April 10, 2025

2:10 – 2:30

OSIS' Role in Conducting Inspections and Remote Regulatory Assessments (RRAs) of Abbreviated New Drug Application (ANDA) *In Vitro* Bioequivalent (BE) Studies

The main objective of this presentation is to provide an overview of how the Office of Study Integrity and Surveillance (OSIS) assesses study conduct of in vitro BE studies submitted in support of ANDAs. It will also provide case studies and common compliance issues.

Tahseen Mirza, PhD
Associate Office Director for Regulatory Affairs (ADRA)
Office of Study Integrity and Surveillance (OSIS)
Office of Translational Sciences (OTS) | CDER

2:30 – 2:50

Questions & Panel Discussion

Jayani Perera, David Green, Fang Yuan, Andrew Idzior, Tahseen Mirza

2:50 – 3:10: BREAK

3:10 – 3:30

Orange Book Marketing Status

This presentation will provide a brief overview of Orange Book publication marketing status changes and 506i, review case examples, and answer commonly asked questions.

Truong Quach, PharmD
Team Lead
DOBPRA | OGDP | OGD | CDER

3:30 – 3:45

What's the Difference? Generic Drugs and Therapeutic Equivalence for 505(b)(2) Applications Under Food and Drug Omnibus Reform Act (FDORA) 2022

This presentation will provide an overview of generic 505(j) vs 505(b)(2) applications seeking therapeutic equivalence under the Food and Drug Omnibus Reform Act (FDORA) of 2022.

Jennifer Miller, PhD
Deputy Office Director
OB | OGD | CDER

3:45 – 4:00

Case Studies of Using Alternate Reference Products or Alternative Bioequivalence (BE) Approaches in Abbreviated New Drug Application (ANDA) Submissions

This presentation will provide case studies of using alternative reference products or alternative BE approaches in ANDA submissions when reference listed drugs (RLDs) and reference standard (RS) products are not available. The purpose is to assist generic applicants in finding alternative approaches to submit ANDAs and demonstrate BE when RLD/RS are not available.

Xiaojian Jiang, PhD
Deputy Division Director
DBII | OB | OGD | CDER

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DAY TWO: Thursday, April 10, 2025

4:00 – 4:20

Common Bioequivalence (BE) Information Requests (IRs): Tips for Facilitating the Review Process

The presentation will provide an overview of information requests (IRs) with a description of more easily correctable deficiencies and their impact on first cycle Bioequivalence (BE) adequacy. Promoting high-quality and complete BE study data and avoiding commonly observed BE deficiencies may decrease the time needed to achieve BE adequacy, which will ultimately facilitate the efficiency of providing the public with access to effective and safe generic drugs.

Fang Lu, PhD
Team Leader
DBI | OB | OGD | CDER

4:20 – 4:40

Questions & Panel Discussion

Truong Quach, Jennifer Miller, Xiaojian Jiang and **Fang Lu**

4:40 – 4:50

Closing Remarks

Kendra S. Stewart, RPh, PharmD
Captain | United States Public Health Service
Deputy Director for Operations
OGD | CDER

4:50: ADJOURN FORUM

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