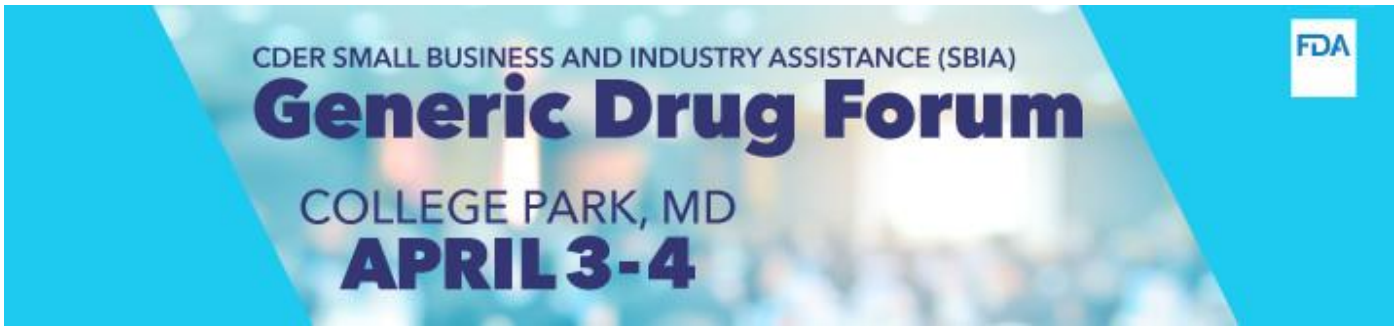

For files and resources, please visit
The Event Page on SBIAevents.com

Add to Your Calendar

AGENDA

Wednesday, April 3, 2019

7:30 AM: Registration Opens

8:00 - 8:15 AM: Administrative Announcements — **Jeff Kelly**

8:15 - 8:30 AM EDT

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

8:30 - 8:50 AM EDT

Keynote from Office of Generic Drugs (OGD)

Sally Choe
Director
Office of Generic Drugs (OGD) | CDER

8:50 - 9:10 AM EDT

Keynote from the Office of Pharmaceutical Quality (OPQ)

Michael Kopcha
Director
Office of Pharmaceutical Quality (OPQ) | CDER

Wednesday, April 3, 2019

SESSION 1: Meeting with the FDA: When and Why

9:10 - 9:40 AM EDT

Complex Product Development

DESCRIPTION

This session will provide details on how and when to request this meeting, examples of what type of advice FDA can and cannot provide, and what and how to prepare for this meeting.

SPEAKERS

Katherine Tyner
Associate Director for Science (Acting)
Immediate Office (IO) | OPQ | CDER

Christine Le
Regulatory Research Officer/Project Manager
Commander, United States Public Health Service
Office of Research and Standards (ORS) | OGD | CDER

9:40 - 10:00 AM EDT

Pre-ANDA Meeting or Controlled Correspondence?

DESCRIPTION

This session will discuss when to use controlled correspondence and when it may be more effective than a meeting. Learn how to obtain agency feedback on inactive ingredients in a proposed generic product. Overview of how pre-submission meetings allow you to discuss the format and content of the ANDA to be submitted, as well as identify items that should be clarified. This session will present practical examples of applications with inadequate information.

SPEAKERS

Bhagwant Rege
Supervisory Chemist
Division of Modified Release Products (DMR)
Office of Lifecycle Drug Products (OLDP) | OPQ | CDER

Kris Andre
Associate Director for Regulatory Affairs
ORS | OGD | CDER

10:00 - 10:15 AM EDT

Panel Questions and Discussion

Katherine Tyner, Christine Le, Bhagwant Rege, Kris Andre

10:15 - 10:30 AM: BREAK

10:30 - 10:50 AM EDT

Mid-cycle Assessment Meetings

DESCRIPTION

This session will provide an overview and tips to make the meeting successful.

SPEAKERS

Andrew Kim
Supervisory Project Manager
Lieutenant Commander, United States Public Health Service
Division of Project Management (DPM)
Office of Regulatory Operations (ORO) | OGD | CDER

Wednesday, April 3, 2019

10:50 - 11:10 AM EDT

Post-complete Response Letter Meetings

DESCRIPTION

This session will provide an overview and tips to make the meeting successful.

SPEAKERS

Andrew Kim
Supervisory Project Manager
Lieutenant Commander, United States Public Health Service
DPMORO) | OGD | CDER

Ankara (Nikki) Yokum
Branch Chief
Office of Program and Regulatory Operations (OPRO)
OPQ | CDER

11:10 - 10:25 AM EDT

Panel Questions and Discussion

Andrew Kim, Nikki Yokum

SESSION 2: Drug Master Files (DMFs)

11:25 - 12:10 PM EDT

Drug Master Files (DMFs) from an Abbreviated New Drug Application (ANDA) Perspective with Q&As

DESCRIPTION

An in-depth discussion about Drug Master Files submitted in support of generic applications. This session will focus on Type II DMFs and will include a discussion of common administrative DMF issues that may negatively affect referencing ANDA submissions.

SPEAKERS

Lauren Woodard
Lieutenant, United States Public Health Service
DMF Reviewer
Division of Lifecycle API
Office of New Drug Products (ONDP)
OPQ | CDER

12:10 - 1:10 PM: LUNCH - On your own. Click HERE for onsite dining options)

SESSION 3: On the Right Track? Common Questions Related to the Orange Book (OB) and to ANDA Submissions

1:10 - 1:30 PM EDT

Orange Book - Its Role in ANDAs

DESCRIPTION

An overview of the Orange Book and its role in ANDA submissions.

SPEAKERS

Alicia Chen
Pharmacist / Acting Team Lead
Division of Legal and Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP) | OGD | CDER

Wednesday, April 3, 2019

1:30 - 2:00 PM EDT

Referencing Approved Drug Products in ANDA Submissions

DESCRIPTION

FDA will address common questions on identifying a reference listed drug, reference standard, and related topics.

SPEAKERS

Susan Levine
Deputy Director
Division of Policy Development (DPD)
OGDP | OGD | CDER

2:00 - 2:30 PM EDT

505(b)(2) NDA or ANDA?

DESCRIPTION

Practical regulatory and scientific advice on selecting the appropriate abbreviated pathway for a proposed product.

SPEAKERS

Elizabeth Friedman
Regulatory Counsel
DPD | OGDP | OGD | CDER

Beth (Duvall) Goldstein
Science Policy Analyst
Office of New Drug Policy (ONDP)
Office of New Drugs (OND) | CDER

2:30 - 3:00 PM EDT

Panel Questions and Discussion

Alicia Chen, Susan Levine, Elizabeth Friedman, Beth Goldstein

Kendra S. Stewart
Captain, United States Public Health Service
Supervisor
Orange Book Staff
DLRS | OGDP | OGD | CDER

3:00 - 3:15 PM: BREAK

SESSION 4: Submissions

3:15 - 3:35 PM EDT

Practical Tips on Using the CDER NextGen Collaboration Portal

DESCRIPTION

Practical examples on common errors and how to avoid them when using the ePortal to submit a pre-ANDA meeting request.

SPEAKERS

Kris Andre
Associate Director for Regulatory Affairs
ORS | OGD | CDER

3:35 - 3:55 PM EDT

Practical Tips on eCTD

DESCRIPTION

This presentation covers points to consider when preparing your eCTD submission and sending to FDA.

SPEAKERS

Jonathan Resnick
Electronic Submissions Capability Team
Office of Business Informatics (OBI)
Division of Data Management Services and Solutions (DDMSS)
Office of Strategic Programs (OSP) | CDER

Wednesday, April 3, 2019

3:55 - 4:15 PM EDT

Submission of Study Data

DESCRIPTION

Presenting recent updates of the FDA Study Data Technical Rejection Criteria, the conformance analysis of the current ANDA submissions, and FDA tools available for helping industry to comply with the mandatory study data requirements.

SPEAKERS

Chao (Ethan) Chen
Director
DDMSS | OBI | OSP | CDER

4:15 - 4:35 PM EDT

Panel Questions and Discussion

Kris Andre, Jonathan Resnick, Ethan Chen

4:35 PM: ADJOURN

5:00 - 6:30 PM: NETWORKING OPPORTUNITY

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

Thursday, April 4, 2019

7:30 AM: Registration Opens

8:00 - 8:10 AM: Administrative Announcements — **Jeff Kelly**

8:10 - 8:20 AM EDT

Welcome

Forest "Ray" Ford, Jr.
Commander, United States Public Health Service
DDI | OCOMM | CDER

SESSION 5: Filing, Assessment, and Refuse to Receive (RTR)

8:20 - 8:50 AM EDT

Filing and Refuse to Receive (RTR)

DESCRIPTION

What went wrong? Learn the top reasons for RTRs and application deficiencies. Attendees will learn steps they can take to avoid these errors happening at their company.

SPEAKERS

Varun Vasudeva
Filing Reviewer

Phuong (Aiden) Nguyen
Filing Reviewer

Division of Filing Review (DFR)
ORO | OGD | CDER

8:50 - 9:05 AM EDT

Assessment Tips

DESCRIPTION

Tips on application submissions.

SPEAKERS

Dat Doan
Captain, United States Public Health Service
Supervisory Project Manager
DPM | ORO | OGD | CDER

9:05 - 9:35 AM EDT

Bioequivalence Case Studies

DESCRIPTION

Examples of adequate and inadequate BE studies FDA accepted or rejected. Troubleshoot bioequivalence challenges.

SPEAKERS

Ke Ren
Associate Director
Division of Bioequivalence III
OGD | CDER

9:35 - 9:55 AM EDT

Panel Questions and Discussion

Aiden Nguyen, Varun Vasudeva, Dat Doan, Ke Ren

Julia Lee, PharmD
Deputy Division Director
DFR | ORO | OGD | CDER

9:55 - 10:10 AM: BREAK

Thursday, April 4, 2019

10:10 - 10:55 AM EDT

Stability Case Studies

DESCRIPTION

One of the top causes for RTR is stability problems. Learn about inadequate and adequate stability submissions and the differences between FDA's and the International Conference on Harmonisation's (ICH) recommendations regarding stability data.

SPEAKERS

Nusrat (Nusie) Motlekar
Senior Policy Lead
Office of Policy of Pharmaceutical Quality (OPPQ)
OPQ | CDER

Frank Holcombe, Jr.
Chemist
OLDP | OPQ | CDER

10:55 - 11:25 AM EDT

Dissolution Case Studies

DESCRIPTION

A top RTR is due to inadequate dissolution. Learn about FDA inadequate and adequate dissolution submissions. Troubleshoot dissolution challenges.

SPEAKERS

Om Anand
Division of Biopharmaceutics
ONDP | OPQ | CDER

11:25 - 11:55 AM EDT

Impurity Case Studies

DESCRIPTION

A top RTR is due to impurity issues. Learn about FDA adequate and inadequate impurity submissions. We will troubleshoot impurity challenges to include Potential Genotoxic Impurity (PGI) assessment in Type II DMFs as well as safety justifications for impurities exceeding International Conference on Harmonisation (ICH) limits in ANDAs.

SPEAKERS

Hongbiao Liao
DMF Reviewer
DLAPI | ONDP | OPQ | CDER

Victoria Keck
Toxicologist
Division of Clinical Review (DCR)
OGD | CDER

11:55 AM - 12:15 PM EDT

Panel Questions and Discussion

Nusie Motlekar, Frank Holcombe, Paul Seo, Hongbio Liao, Victoria Keck

12:15 - 1:15 PM: LUNCH - On your own. Click HERE for onsite dining options

1:15 - 1:55 PM EDT

Types of Fees and Q&A

DESCRIPTION

Learn the types of fees and applicability to your facilities/products.

SPEAKERS

Donal Parks
Director
Division of User Fee Management and Budget Formulation
Office of Management (OM) | CDER

Thursday, April 4, 2019

Session 6: Manufacturing and Quality

1:55 - 2:25 PM EDT

Continuous Manufacturing with a Generic Perspective

DESCRIPTION

Learn the current FDA perspective on the development and implementation of continuous manufacturing as a platform technology for multiple products.

SPEAKERS

Sau (Larry) Lee
Director
Office of Testing and Research (OTR)
OPQ | CDER

2:25 - 2:40 PM: BREAK

2:40 - 3:25 PM EDT

Manufacturing Process and Controls: How to Avoid Major Assessment Issues Turning into Potential Deficiencies/Approvability Issue

DESCRIPTION

Case studies on how common assessment issues could potentially turn into a major deficiency/approvability issue.

SPEAKERS

Yaodong (Tony) Huang
Chemist/Acting Quality Assessment Lead
Office of Process and Facilities (OPF)
OPQ | CDER

3:25 - 3:55 PM EDT

Deficiencies and Observations from Facility Evaluations and Inspections

DESCRIPTION

Discussion of recent 483s from ANDA inspections.

SPEAKERS

Vidya Pai
Chemist/ Acting Quality Assessment Lead
OPF | OPQ | OGD | CDER

3:55 - 4:25 PM EDT

Panel Questions and Discussion

Larry Lee, Tony Huang, Vidya Pai

4:25 PM: ADJOURN

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