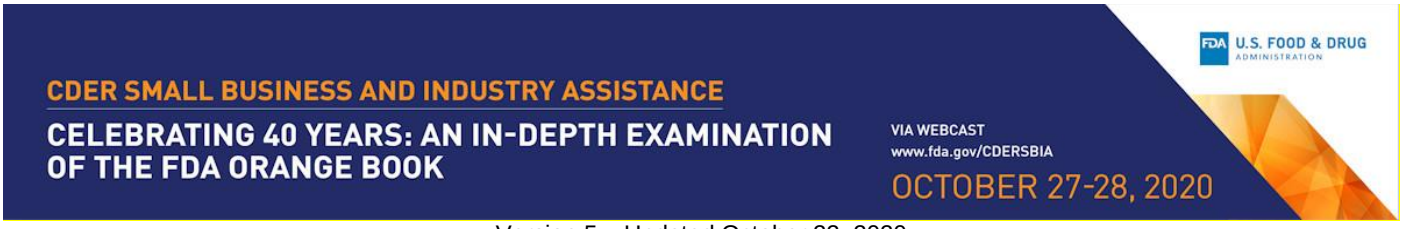

Version 5 – Updated October 22, 2020

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

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AGENDA

All times are Eastern (EDT UTC-4)

View Start Time on World Clock

DAY ONE: Tuesday, October 27, 2020

9:15 – 9:30

Welcome and Administrative Overview

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

9:30 – 9:40

Opening Remarks

Opening remarks noting the 40th anniversary of the Orange Book.

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

9:40 – 10:05

FDA's Orange Book: A Historical Review of 40 Years

This session will provide a history of the Orange Book including why the Orange Book was established, changes and enhancements that have occurred over the years, who uses the Orange Book and for what purposes, as well as the FDA team that makes the publication happen.

Kendra Stewart
CAPT, USPHS
Division of Legal and Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP)
OGD | CDER

Your SBIA Hosts for Day One

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

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

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

DAY ONE: Tuesday, October 27, 2020

10:05 – 10:30

Orange Book 101: An Overview of FDA's Orange Book

This high-level presentation will cover the "nuts and bolts" content of the Orange Book, including how and when updates are made and information on the many workstreams involved in Orange Book publication.

Camille Smith
DLRS | OGDP | OGD

10:30 - 10:50: BREAK

10:50 – 11:35

How to Update Orange Book Information and Related Considerations: Marketing Status Changes: 506I reporting, Drug Shortages, and Transfer of Ownership Updates

This session will discuss updates to Orange Book information including transfer of ownership of an application, application holder name changes, reports required by section 506I of the Federal Food, Drug, and Cosmetic Act, and user fee implications.

Kendra Stewart

Kun Shen
CDR, USPHS
DLRS | OGDP | OGD | CDER

Eunice Chung-Davies
CAPT, USPHS
Division of User Fee Management and Budget Formulation (DUFMBF)
Office of Management (OM) | CDER

11:35 – 11:55

Q&A Panel

Kendra Stewart, Kun Shen, Eunice Chung-Davies and Elizabeth Friedman
Division of Policy Development (DPD) OGDP | OGD | CDER

11:55 - 1:00: LUNCH BREAK

1:00 – 1:15

An Overview of FDA's Patent Listing Process

This session will discuss the patent listing process including a walkthrough of Forms 3542/3542a and how the forms are processed. The session will also discuss changes to Form 3542 instructions and how to avoid frequent mistakes.

Kun Shen

1:15 – 2:10

Changes to Orange Book Patent Information

This session will discuss how to submit and make changes to patent information, patent delistings, and patent expiration date extensions. We will also discuss what patent information to submit in connection with supplement approvals, including "Rx-to-OTC" switches.

Alicia Chen
DLRS | OGDP | OGD | CDER

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DAY ONE: Tuesday, October 27, 2020

2:10 - 2:30

Q&A Panel

Kun Shen, Alicia Chen and Janice Weiner
Division of Regulatory Policy I (DRPI)
Office of Regulatory Policy (ORP) | CDER

2:30 – 2:50: BREAK

2:50 – 3:20

The Patent Information Dispute Process

This session will explain the patent information challenge process, FDA's patent dispute list, and the single 15-day period for corrections to Form 3542.

Alicia Chen
DLRS | OGDP | OGD | CDER

3:20 – 4:00

Best Practices for 505(b)(2) and ANDA Applicants

This session will discuss best practices for 505(b)(2) and ANDA applicants to address patent information listed in the Orange Book, and how and when to respond to changes to patent information.

Mary Ann Holovac
Division of Regulatory Policy (DRP)
Office of New Drug Policy (ONDP)
Office of New Drugs (OND)

Andrew Coogan
DLRS | OGDP | OGD | CDER

4:00 – 4:20

Q&A Panel

Alicia Chen, Mary Ann Holovac, Andrew Coogan, and Jennifer Gerton
Office of the Chief Counsel (OCC)

4:20 – 4:25

Closing Statements

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

4:25: DAY ONE ADJOURN

All times shown are Eastern (EDT UTC-4)

DAY TWO: Wednesday, October 28, 2020

9:00 – 9:10

Welcome and Administrative Overview

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

9:10 – 9:15

Opening Remarks

Kendra Stewart
CAPT, USPHS
DLRS | OGDP | OGD | CDER

Your SBIA Hosts for Day Two

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

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

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

9:15 – 9:30

Orange Book Exclusivity: An Introduction and Overview

This session will provide an overview of the types of exclusivities that are listed in the Orange Book and information on publication of exclusivities.

Truong Quach
DLRS|OGDP|OGD

9:30 – 10:05

Orange Book Exclusivity: Part I - NCE and 3-Year

This session includes presentations on New Chemical Entity (NCE) and 3-year exclusivities, and impacts on ANDAs and 505(b)(2)s.

Nisha Shah
Division of Regulatory Policy I (DRPIV)
Office of Regulatory Policy (ORP)

10:05 – 10:25

Q&A Panel

Truong Quach, Nisha Shah
Alicia Chen
and Christopher Pruitt
DLRS | OGDP | OGD | CDER

10:25 – 10:45: BREAK

All times shown are Eastern (EDT UTC-4)

DAY TWO: Wednesday, October 28, 2020

10:45 – 11:25

Orange Book Exclusivity: Part II - Pediatric, Orphan, and GAIN

This session will provide information on pediatric, Generating Antibiotic Incentives Now (GAIN) , and orphan exclusivities and impacts on ANDAs and 505(b)(2)s

Kristiana Brugger
Division of Regulatory Policy IV (DRPIV) Office of Regulatory Policy (ORP) | CDER

Aaron Friedman
Office of Orphan Products Development (OOPD)
Office of Clinical Policy and Programs (OCPP)
Office of the Commissioner (OC)

Katherine Schumann
Division of Regulatory Policy (DRP)
Office of New Drug Policy (ONDP)
OND | CDER

11:25 – 12:05

Orange Book Exclusivity: Part III - 180-Day and Competitive Generic Therapy Exclusivities

This session will provide information on 180-Day and Competitive Generic Therapy exclusivities, which apply to generic drugs.

Jonathan Hughes
Division of Policy Development (DPD)
Office of Generic Drug Policy (OGDP)
OGD | CDER

Mindy Ehrenfried
DPD | OGDP | OGD | CDER

12:05 – 12:25

Q&A Panel

Kristiana Brugger, Aaron Friedman, Katherine Schumann, Jonathan Hughes, Mindy Ehrenfried

12:25 - 1:30: LUNCH BREAK

1:30 – 1:45

Orange Book: An Overview of Therapeutic Equivalence

This session will discuss the basics of therapeutic equivalence and how FDA determines if drug products are therapeutically equivalent (TE).

Elizabeth Friedman
DPD | OGDP | OGD | CDER

1:45 – 2:00

Q&A Panel

Elizabeth Friedman, Kendra Stewart, and **James Myers**
DRP | ONDP | OND | CDER

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DAY TWO: Wednesday, October 28, 2020

2:00 – 2:30

Referencing Approved Drug Products in ANDA Submissions

This session will discuss referencing approved drug products in an ANDA, how to request designation of a reference listed drug or different reference standard, and how to choose the right reference product for your submission.

James Hanratty
DPD | OGDP | OGD | CDER

Timothy Kim
DLRS | OGDP | OGD | CDER

2:30 – 2:50

Q&A Panel

James Hanratty, Timothy Kim
Kendra Stewart
and Susan Levine
DPD | OGDP | OGD | CDER

2:50 – 3:10: BREAK

3:10 – 3:20

Orange Book: Looking Towards the Future

Discuss the recent Federal Register notices soliciting feedback on the Orange Book in general as well as on patent listings and potential Orange Book enhancements.

Kendra Stewart
DLRS | OGDP | OGD | CDER

3:20 – 3:30

Closing Remarks

Maryll Toufanian
Director, OGDP

3:30: ADJOURN

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