AGENDA
All times are Eastern (EDT UTC-4)

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

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<tr>
<td>2:10 - 2:30</td>
<td>Q&amp;A Panel</td>
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<td>Kun Shen, Alicia Chen and Janice Weiner</td>
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<td>2:30 – 2:50:</td>
<td>BREAK</td>
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<td>2:50 – 3:20</td>
<td>The Patent Information Dispute Process</td>
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<td>3:20 – 4:00</td>
<td>Best Practices for 505(b)(2) and ANDA Applicants</td>
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<td>Mary Ann Holovac</td>
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<td>Andrew Coogan</td>
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<td>4:00 – 4:20</td>
<td>Q&amp;A Panel</td>
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<td>Alicia Chen, Mary Ann Holovac, Andrew Coogan, and Jennifer Gerton</td>
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<td>Closing Statements</td>
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### DAY TWO: Wednesday, October 28, 2020

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<td>9:30 – 10:05</td>
<td>Orange Book Exclusivity: An Introduction and Overview</td>
<td>Truong Quach DLRS</td>
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<td>10:05 – 10:25</td>
<td>Q&amp;A Panel</td>
<td>Truong Quach, Nisha Shah Alicia Chen and Christopher Pruitt DLRS</td>
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**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
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