



**CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE**

**CELEBRATING 40 YEARS: AN IN-DEPTH EXAMINATION OF THE FDA ORANGE BOOK**

VIA WEBCAST  
www.fda.gov/CDERSBIA

**OCTOBER 27-28, 2020**

Version 5 – Updated October 22, 2020

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**AGENDA**

All times are Eastern (EDT UTC-4)

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**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

**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 | OGD | 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 | OGD | 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**

**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**

**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