AGENDA

All times are Eastern (EDT UTC-4)

View Start Time on World Clock

Wednesday, October 13, 2021

<table>
<thead>
<tr>
<th>Time</th>
<th>Description</th>
<th>Speaker/Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:45 - 9:00</td>
<td>Welcome and Overview</td>
<td>Brenda Stodart, Captain (CAPT), United States Public Health Service Director, Small Business and Industry Assistance (SBIA) Division of Drug Information (DDI)</td>
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<tr>
<td>9:00 – 9:05</td>
<td>Welcome Remarks from the Office of Compliance</td>
<td>Don D. Ashley, Director Office of Compliance (OC)</td>
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<tr>
<td>9:05 – 9:20</td>
<td>Keynote</td>
<td>Paul Loebach, Branch Chief Drug Registration and Listing Branch (DRLB) Division of Labeling, Registration and Unapproved Drugs (DLRUD) Office of Unapproved Drugs and Labeling Compliance (OUDLC)</td>
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</tbody>
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Your SBIA Host

Forest "Ray" Ford, Jr., PharmD CAPT, USPHS, Pharmacist SBIA | DDI | OCOMM | CDER
Wednesday, October 13, 2021

9:20 – 9:30
FDA Website: Resources Available to You

Topics include demonstrations of:
- A walkthrough of the DRLS website including:
  - The National Drug Code (NDC) Directory
  - Drug Establishments Current Registration Site (DECRS)
  - 503B Facilities
  - SPL webpage
- Where to find helpful information without having to send an email

Don Duggan
Team Lead, Helpdesk Operations Team (HOT)
DRLB | DLRUD | OUDLC | CDER

9:30 – 10:25
Drug Establishment Registration 101 – The Basics

Topics include demonstrations of:
- How to create and submit various registration and listing submissions using CDER Direct including:
  - Establishment Registration and Updates
  - Establishment Deregistration
  - Labeler Code Request

Regie Samuel
Technical Information Specialist
HOT | DRLB | DLRUD | OUDLC | CDER

Vikas Arora
Pharmacist
Office of Program and Regulatory Operations (OPRO)
OC | CDER

Puii Huber
Technical Information Specialist
HOT | DRLB | DLRUD | OUDLC | CDER

10:25 – 10:40: BREAK

10:40 – 11:35
Drug Listing 101 – The Basics

Topics include demonstrations of:
- Drug Listing – including content of labeling
- Delisting
- NDC Reservation
- Blanket No Change Certification

Soo Jin Park
LCDR, USPHS
Regulatory Officer

David Mazyck
Consumer Safety Officer

Troy Cu
Technical Information Specialist

Regie Samuel
Technical Information Specialist
DRLB | DLRUD | OUDLC | CDER
### Wednesday, October 13, 2021

#### 11:35 – 11:45
**The National Drug Code (NDC): Rules for Assigning and Changing**

<table>
<thead>
<tr>
<th>Topics include:</th>
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<tbody>
<tr>
<td>• A description on the structure of the NDC</td>
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<tr>
<td>• When to assign a new NDC and which segment to change.</td>
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_Soo Jin Park_  
**LCDR, USPHS**  
*Regulatory Officer*  
Data Quality and Compliance Team (DQCT)  
DRLB | DLRUD | OUDLC | CDER

#### 11:45 – 12:05
**503B Human Drug Compounding Outsourcing Facility Registration and Product Reporting 101 – The Basics**

<table>
<thead>
<tr>
<th>Topics include demonstrations of:</th>
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<tbody>
<tr>
<td>• How to create and submit registration and 6-month product report submissions using CDER Direct</td>
</tr>
</tbody>
</table>

_Troy Cu_  
*Technical Information Specialist*  
HOT | DRLB | DLRUD | OUDLC | CDER

#### 12:05 – 12:30
**Q&A Panel**

_All Speakers_

#### 12:30 – 1:00: LUNCH BREAK

#### 1:00 – 1:15
**OMUFA Fees for Registered OTC Drug Manufacturers**

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<thead>
<tr>
<th>Topics include:</th>
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<tbody>
<tr>
<td>• An overview of the Over-The-Counter Monograph User Fee Program (OMUFA)</td>
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<tr>
<td>o Which operations are subject to fees</td>
</tr>
<tr>
<td>o When fees are due</td>
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</tbody>
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_Matt Brancazio_  
**CAPT, USPHS**  
*Branch Chief, Policy and Operations Branch*  
Division of User Fee Management (DUFM)  
Office of Management (OM) | CDER

#### 1:15 – 2:00
**Tips, Techniques, and Common Mistakes with Submissions**

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<tr>
<th>Topics include:</th>
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<tr>
<td>• Quick presentations focusing on common errors and issues with submissions, including:</td>
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<tr>
<td>o Incorrect strength</td>
</tr>
<tr>
<td>o How to create a kit listing</td>
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<tr>
<td>o Combination product designation</td>
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<tr>
<td>o Requesting overrides</td>
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</table>

_Tasneem Hussain_  
*Pharmacist*

_Troy Cu_  
*Technical Information Specialist*

_Paul Loebach_  
*Branch Chief*

_DRLB | DLRUD | OUDLC | CDER_

#### 2:00 – 2:15
**Compliance Program**

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<thead>
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<th>Topics include:</th>
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<tr>
<td>• An overview of registration and listing compliance program in addressing inaccurate submissions to the Agency</td>
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_Leyla Rahjou-Esfandiary_  
*Team Lead*

_DQCT | DRLB | DLRUD | OUDLC | CDER_

#### 2:15 – 2:30: BREAK
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Topics</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>2:30 – 2:50</td>
<td>Registration and Listing Deficiency Letters</td>
<td>• How the move forward with corrections and possible submission errors</td>
<td>Tasneem Hussain, Pharmacist, DQCT</td>
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</table>
| 2:50 – 3:15| Current Compliance Projects: U.S. Agents – Verification Initiative & Listing Inactivation Project | • How FDA is handling foreign establishments with incorrect or out-of-date US agent designations  
• Overview of FDA’s Drug Listing Inactivation project | Leyla Rahjou-Esfandiary, Team Lead, DQCT | DRLB | DLRUD | OUDLC | CDER  
Paul Loebach, Branch Chief, DRLB | DLRUD | OUDLC | CDER |
| 3:15 – 3:45| Submission Troubleshooting Exercise                                           | • Hands-on problem solving and trouble-shooting exercises               | Julian Chun, Pharmacist, DQCT | DRLB | DLRUD | OUDLC | CDER   |
| 3:45 – 4:15| Q&A Panel                                                                    |                                                                        | All Speakers                               |
| 4:15 – 4:25| Closing Remarks                                                               |                                                                        | Paul Loebach, Branch Chief, DRLB | DLRUD | OUDLC | CDER   |
| 4:25 -     | ADJOURN                                                                      |                                                                        |                                             |