

CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE

ELECTRONIC DRUG REGISTRATION AND LISTING (eDRLS) USING CDER DIRECT



www.fda.gov/CDERSBIA

OCT 13, 2021

Version 8, October 12, 2020
(use link below to check for updates)

For files and resources, please visit
[The Event Page on SBIAevents.com](https://www.sbiaevents.com)

[Add to Your Calendar](#)

AGENDA

All times are Eastern (EDT UTC-4)

[View Start Time on World Clock](#)

Wednesday, October 13, 2021

8:45 - 9:00

Welcome and Overview

Brenda Stodart

*Captain (CAPT), United States Public Health Service
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation & Research (CDER)*

9:00 - 9:05

Welcome Remarks from the Office of Compliance

Don D. Ashley

*Director
Office of Compliance (OC) | CDER*

9:05 - 9:20

Keynote

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) | OC | CDER*

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

Topics include:

- A description on the structure of the NDC
- When to assign a new NDC and which segment to change.

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

Topics include demonstrations of:

- How to create and submit registration and 6-month product report submissions using CDER Direct

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

Topics include:

- An overview of the [Over-The-Counter Monograph User Fee Program](#) (OMUFA)
 - Which operations are subject to fees
 - When fees are due

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

Topics include:

- Quick presentations focusing on common errors and issues with submissions, including:
 - Incorrect strength
 - How to create a kit listing
 - Combination product designation
 - Requesting overrides

Tasneem Hussain
Pharmacist

Troy Cu
Technical Information Specialist

Paul Loebach
Branch Chief
 DRLB | DLRUD | OUDLC | CDER

2:00 – 2:15

Compliance Program

Topics include:

- An overview of registration and listing compliance program in addressing inaccurate submissions to the Agency

Leyla Rahjou-Esfandiary
Team Lead
 DQCT | DRLB | DLRUD | OUDLC | CDER

2:15 – 2:30: BREAK

Wednesday, October 13, 2021

2:30 – 2:50

Registration and Listing Deficiency Letters

Topics include:

- How the move forward with corrections and possible submission errors

Tasneem Hussain

Pharmacist

DQCT | DRLB | DLRUD | OUDLC | CDER

2:50 – 3:15

Current Compliance Projects:

U.S. Agents – Verification Initiative & Listing Inactivation Project

Topics include:

- 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

Topics include:

- 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