CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE

ELECTRONIC DRUG REGISTRATION AND LISTING (eDRLS) USING CDER DIRECT

U.S. FOOD & DRUG ADMINISTRATION

www.fda.gov/CDERSBIA

OCT 13, 2021

Version 3, September 1, 2020
(use link below to check for updates)

For files and resources, please visit
The Event Page on 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 – 9:15

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 Hosts

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

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

Wednesday, October 13, 2021

9:15 – 9:25

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

9:25 – 10:05

Drug 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
- ***Q&A session***

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

10:05 – 10:55

Drug Listing 101 – The Basics

Topics include demonstrations of:

- Drug Listing – including content of labeling
- Delisting
- NDC Reservation
- Blanket No Change Certification
- ***Q&A session***

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

10:55 – 11:10: BREAK

Wednesday, October 13, 2021

11:10 – 11:30

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.
- ***Q&A Session***

Soo Jin Park
LCDR, USPHS
Regulatory Officer
Data Quality and Compliance Team (DQCT)
DRLB | DLRUD | OUDLC | CDER

11:30 – 12:00

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
- ***Q&A session***

Troy Cu
Technical Information Specialist
HOT | DRLB | DLRUD | OUDLC | CDER

12:00 – 12:30: LUNCH BREAK

12:30 – 12:45

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
- ***Q&A Session***

Matt Brancazio
CAPT, USPHS
Branch Chief, Policy and Operations Branch
Division of User Fee Management (DUFM)
Office of Management (OM) | CDER

12:45 – 1:30

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
- ***Q&A session***

Tasneem Hussain
Pharmacist

Troy Cu
Technical Information Specialist

Paul Loebach
Director

DRLB | DLRUD | OUDLC | CDER

1:30 – 1:45

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

1:45 – 2:00: BREAK

2:00 – 2:15

What if I Get a Deficiency Letter?

Topics include:

- How the move forward with corrections and possible submission errors

Tasneem Hussain
Pharmacist
DQCT | DRLB | DLRUD | OUDLC | CDER

2:15 – 2:30

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
Director
DRLB | DLRUD | OUDLC | CDER

2:30 – 3:15

Submission Troubleshooting Exercise

Topics include:

- Hands-on problem solving and trouble-shooting exercises

Julian Chun
Pharmacist
DQCT | DRLB | DLRUD | OUDLC | CDER

3:15 – 3:45

Q&A Panel

All Speakers

3:45 – 4:00

Closing Remarks

Paul Loebach
Branch Chief
DRLB | DLRUD | OUDLC | CDER

4:00 p.m. - ADJOURN