Version 5 – September 11, 2026

FDA's Drug Registration and Listing Workshop: Compliance, Regulatory, and Submission Updates

Tuesday, September 29, 2026

AGENDA

All times are Eastern (UTC-5)
View Start Time on World Clock

8:45 - 9:00

Welcome and Overview

Brenda Stodart, PharmD, BCGP, RAC-US
Captain, United States Public Health Service
Director, Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Center for Drug Evaluation and Research (CDER) | FDA

Your SBIA Host

Kori Adair, PharmD
Pharmacist
SBIA | DDI | CDER

9:00 - 9:15

Keynote

Jill P. Furman, JD
Director
Office of Compliance (OC) | CDER

9:15 – 9:45

Foundation and Requirements

- Regulatory Foundation and Requirements
- Foundations of Registration and Listing Submissions

Stephanie Williams, JD
Regulatory Counsel
Drug Registration & Listing Branch (DRLB)
Division of Labeling, Registration and Unapproved Drugs (DLRUD)
Office of Unapproved Drugs and Labeling Compliance (OUDLC) | CDER

Lalnunpuii Huber, MS
Lead Public Health Analyst from DRLB

9:45 - 10:30

Submission Reminders and Updates

- How to make a successful submission
- Validation Rules – Reminders and Updates
- Data Publication

Troy Cu
Technical Information Specialist from DRLB

Regie Samuel
Technical Information Specialist from DRLB

Jose Cabrera
Technical Information Specialist from DRLB

10:30 - 10:45

Q&A Panel

Stephanie Williams, Lalnunpuii Huber, Regie Samuel, Troy Cu, and **Jose Cabrera**

10:45 – 11:00: BREAK

11:00 - 11:45

Regulatory Reminders and Updates

- Repackagers and Relabelers
- Mergers/ Acquisitions
- Data Inactivation

Jeffrey Trunzo, RPh, MBA
Consumer Safety Officer from DRLB

Yogesh Paruthi, PharmD
Consumer Safety Officer from DRLB

Vikas Arora, PharmD
Consumer Safety Officer from DRLB

11:45 - 12:00

Q&A Panel

Jeffrey Trunzo, Yogesh Paruthi, and **Vikas Arora**

12:00 – 1:15: LUNCH BREAK

1:15 – 1:45

Drug Amount Reporting Compliance

- Drug Amount Reporting Requirements and Compliance
- Drug Amount Reporting Submissions and Latest Updates

Brad Pace, JD
Associate Director
Office of Unapproved Drugs and Labeling Compliance (OUDLC) | CDER

Obinna Ugwu-Oju, MS
Division Director
Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ) | CDER

Leyla Rahjou-Esfandiary, PharmD
Branch Chief
Drug Registration & Listing Branch (DRLB)
Division of Labeling, Registration and Unapproved Drugs (DLRUD)
OUDLC | CDER

1:45 – 2:00

Q&A Panel

Brad Pace, Obinna Ugwu-Oju, and **Leyla Rahjou-Esfandiary**

2:00 – 2:15: BREAK

2:15 – 2:45

Revising the National Drug Code Format and Drug Label Barcode Requirements

Leyla Rahjou-Esfandiary, PharmD
Branch Chief from DRLB

2:45 – 3:55

Panel Discussion

***Moderated by*:**

Julian Chun, PharmD, MBA
Lead Public Health Analyst from DRLB

***Panelists*:**

Leyla Rahjou-Esfandiary, PharmD
Branch Chief from DRLB

Joan Dailey, JD
Regulatory Counsel
Division of Regulatory Policy II (DRP II)
Office of Regulatory Policy (ORP) | CDER

Sayyem Akbar, PharmD, MBA, BCACP, PhC
Lieutenant Commander, United States Public Health Service
Prescription Drugs Branch (PDB)
Division of Unapproved Drugs and Labeling (DUDL)
OUDLC | CDER

Lysette Deshields, PharmD, JD
Commander, United States Public Health Service
Sr. Program Management Officer
Supply Chain Security Branch (SCSB)
Division of Supply Chain Integrity (DSCI)
Office of Drug Security, Integrity and Response (ODSIR) | CDER

3:55 – 4:00

SBIA Closing

Kori Adair, PharmD
Pharmacist
SBIA | DDI | CDER

4:00 – ADJOURN