CDER Small Business and Industry Assistance (SBIA)

Workshop

Version 1 – July 13, 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

**9:15 – 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**
*Technical Information Specialist from DRLB*

**9:45 - 10:30**

## Submission Reminders and Updates

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

**Regie Samuel**
*Technical Information Specialist from DRLB*

**Troy Cu**
*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

**Soo Jin Park, PharmD**
*Lieutenant Commander,* United States Public Health Service
*Regulatory 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

**Soo Jin Park, 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

**1:45 – 2:00**

## Q&A Panel

**Brad Pace, Obinna Ugwu-Oju,** and joined by**:**

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

**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**
*Consumer Safety Officer 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**