

Workshop



Version 2 – July 17, 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

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