



Small Business and Industry Assistance Electronic Drug Registration and Listing (eDRLS) Using CDER Direct 2024



Version 3, August 9, 2024
(use link below to check for updates)

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AGENDA

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

Thursday, September 12, 2024

8:45 - 9:00

Welcome and Overview

Brenda Stodart, PharmD, BCGP, RAC-US

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

9:00 – 9:15

Keynote

Matthew Lash, JD

*Deputy Director
Office of Compliance (OC)
CDER | FDA*

Your SBIA Host

Nora Lim, PharmD, BCPS

*Lieutenant Commander | USPHS | Pharmacist
SBIA | DDI | OCOMM | CDER | FDA*

Thursday, September 12, 2024

9:15 – 10:30

Registering Your Drug Manufacturing Establishment Using CDER Direct

Topics include:

- CDER Direct Establishment Registration Demo
- Establishment Registration Highlights
- Complying with Establishment Registration Requirements

Regie Samuel
Technical Information Specialist
 Drug Registration and Listing Branch (DRLB)
 Division of Labeling, Registration, and Unapproved Drugs (DLRUD)
 Office of Unapproved Drugs & Labeling Compliance (OUDLC)
 CDER | FDA

Jose Cabrera
Technical Information Specialist
 DRLB | DLRUD | OUDLC | CDER | FDA

Tasneem Hussain, PharmD
Consumer Safety Officer
 DRLB | DLRUD | OUDLC | CDER | FDA

10:30 – 10:45: BREAK

10:45 - 11:30

Requesting a Labeler Code from FDA

Topics include:

- CDER Direct Labeler Code Request Demo
- Labeler Code Request Highlights
- Complying with Labeler Code Request Requirements

Puii Huber
Technical Information Specialist
 DRLB | DLRUD | OUDLC | CDER | FDA

Laurie Simonds, GWCPM
Technical Information Specialist
 DRLB | DLRUD | OUDLC | CDER | FDA

Vikas Arora, PharmD
Consumer Safety Officer
 DRLB | DLRUD | OUDLC | CDER | FDA

11:30 - 12:00

Q&A Panel

All Speakers

12:00 – 1:00: LUNCH BREAK

Thursday, September 12, 2024

1:00 – 2:30

Listing Your Drug Using CDER Direct

Topics include:

- CDER Direct Drug Listing Demo
- Listing Updates and Blanket No Change Certification Demo
- Drug Listing Highlights
- Complying with Drug Listing Requirements

Troy Cu

Technical Information Specialist

DRLB | DLRUD | OUDLC | CDER | FDA

Yogesh Paruthi, PharmD

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

Vikas Arora, PharmD

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

Tasneem Hussain, PharmD

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

2:30 – 3:00

National Drug Code

Topics include:

- NDC Reservation
- Future Format of the National Drug Code
- NDC Assignment to Drugs

David Mazyck

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

Leyla Rahjou-Esfandiary, PharmD

Branch Chief

DRLB | DLRUD | OUDLC | CDER | FDA

Soo Jin Park, PharmD, MS

Lieutenant Commander | USPHS | Regulatory Officer

DRLB | DLRUD | OUDLC | CDER | FDA

3:00 – 3:15: BREAK

Thursday, September 12, 2024

3:15 – 3:45

Recent Updates

Topics include:

- OTC Drug Listing Updates and Validation
- Drug Amount Reporting for Listed Drugs
- Who Should Not Register or List

Leyla Rahjou-Esfandiary, PharmD

Branch Chief

DRLB | DLRUD | OUDLC | CDER | FDA

Obinna Ugwu-Oju, MS

Division Director

Office of Pharmaceutical Quality (OPQ)

Office of Quality Surveillance (OSI)

CDER | FDA

Yogesh Paruthi, PharmD

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

3:45 – 4:15

Case Studies

Julian Chun, PharmD, MBA

Consumer Safety Officer

DRLB | DLRUD | OUDLC | OC | CDER | FDA

4:15 – 4:40

Q&A Panel

All Speakers

4:40 – 4:45

SBIA Closing

Nora Lim, PharmD, BCPS

Lieutenant Commander | USPHS | Pharmacist

SBIA | DDI | OCOMM | CDER | FDA

4:45 - ADJOURN